

**Selection Criteria:**

|                            |                    |             |     |             |
|----------------------------|--------------------|-------------|-----|-------------|
| Product Name:              | [EPIPEN,EPIPEN JR] |             |     |             |
| Product Active Ingredient: |                    |             |     |             |
| Active Ingredient:         |                    |             |     |             |
| Active Moiety:             |                    |             |     |             |
| FDA Received Date:         | From:              | 01-Jan-2012 | To: | 15-May-2018 |
| MedDRA® Version* :         | 21.0               |             |     |             |
| Total Cases**:             | 2114               |             |     |             |
| Number of Pages:           | 533                |             |     |             |

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

\*. "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

\*\*. "Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

| Field Heading     | Definition  |
|-------------------|---|
| FDA Received Date | The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available. |
| Case #            | A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.   |
| Case Type         | There are three case types in FAERS:<br>Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events<br>Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting.<br>Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers.   |
| Health Prof       | Indicates whether the initial source who provided information about the event is a health professional. Possible values are; Y - Yes, N – No or the field is blank if it was not reported   |
| Outcomes          | Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.  |
| Mfr Control #     | The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.  |
| 503B Facility     | Indicates whether the organization that sent the report to FDA is an outsourcing facility. An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the Food, Drug, and Cosmetic Act. Possible value is Y – Yes.   |
| Age               | The patient's age, with age unit, based on information provided in the report.  |
| Sex               | Patient sex (Male, Female, Unknown).  |

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|                |   |
|----------------|---|
| Country        | The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.   |
| Preferred Term | A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products. |
| Product        | Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.  |
| Comp.          | Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.  |
| OTC            | Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.  |
| Role           | There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.   |
| Route          | Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).  |
| Dosage Text    | Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.  |
| Duration       | The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.  |
| Mfr            | The manufacturer of the product, as indicated in the report.  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------------------|--------------------------------|-----------------|------------|----------------|
| 03-Jan-2012   | 8304794        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-K201100543              |                                | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                    |                    | S               |                                       | Unk                            |                 | Pfizer     |                |
|   | Tramadol       |                    |                    | C               |                                       | 50 Mg, Every 4 Hours As Needed |                 |            |                |
|   | Flexeril       |                    |                    | C               |                                       | 5 Mg, As Needed                |                 |            |                |
|   | Zoloft         |                    |                    | C               | Occlusive dressing technique          | 100 Mg, 1x/Day                 |                 |            |                |
|   | Valium         |                    |                    | C               | Oral                                  | 5 Mg, As Needed                |                 |            |                |
|   | Hydrocodone    |                    |                    | C               | Oral                                  | Unk                            |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Jan-2012   | 8373376        | DIRECT             |                    |                 |                                       |                                |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u> |                |
| Intercepted Drug Dispensing Error; Medication Error                               | Epipen Jr      |                    |                    | S               |                                       | Injection                      |                 |            |                |
|   | Epipen         |                    |                    | S               |                                       | Auto-Injection                 |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Jan-2012   | 8323230        | EXPEDITED (15-DAY) | N                  | OT              | GB-PFIZER INC-2012002140              |                                | 72 YR           | Male       | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>             | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Overdose; Chest Pain; Dyspnoea; Incorrect Route Of Drug Administration | Epipen         |                    |                    | S               | Intravenous (not otherwise specified) | Unk                            |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>           | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Jan-2012   | 8281347        | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2011298135              |                                | 23 YR           | Female     | USA            |

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| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective;<br>Dyspnoea  | Epipen         |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Feb-2012  | 8322241        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-<br>2011315825 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen         |                    |                    | S               |                              |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Feb-2012  | 8338948        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-<br>2012006892 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With<br>Device   | Epipen         |                    |                    | S               |                              |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Feb-2012  | 8320098        | EXPEDITED (15-DAY) | Y                  | OT              | CA-PFIZER INC-<br>2011314930 |                      |                 | Male       | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Contusion;<br>Expired Product<br>Administered; Injection<br>Site Coldness; Injection<br>Site Pallor; Pain | Epipen         |                    |                    | S               |                              |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Feb-2012  | 8326303        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-<br>2012002151 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injury Associated   | Epipen         |                    |                    | S               |                              |                      |                 | Pfizer     |                |

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With Device

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 06-Feb-2012              | 8327922        | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-2012002472 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 06-Feb-2012   | 8350290        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2012017040 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen Jr      |                  |                    | S               |                          |                      |                 | Pfizer     |                |

| <u>FDA Received Date</u>      | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 14-Feb-2012                   | 8384238        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2011307739 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2012   | 8422150        | DIRECT           | N                  |                 |                      |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Failure Of Child Resistant Mechanism For Pharmaceutical Product; Foreign Body; Injury Associated With Device | Epipen         |                  |                    | S               |                      |                      |                 | Dey        |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 27-Feb-2012  | 8281358        | NON-EXPEDITED    | Y                  | OT              | US-PFIZER INC-2011298125 |                      | 22 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Feb-2012  | 8387834        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2012027939 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Feeling Jittery  | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Feb-2012  | 8387846        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2012027833 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hyperhidrosis; Injection Site Discomfort; Injection Site Mass; Nausea; Nervousness; Tremor | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Feb-2012  | 8390762        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-2012027983 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Injury Associated With Device   | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 28-Feb-2012   | 8407209        | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-2012030599 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen         |                    |                    | S               |                          | 0.3 MI, Unk          | 1 DAY           | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Feb-2012   | 8431595        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012047166 |                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Discomfort; Injury Associated With Device      | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Feb-2012   | 8429524        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2012049135 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Mar-2012   | 8424959        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2012047048 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen         |                    |                    | S               |                          | 0.3 Mg, Unk          | 1 DAY           | Pfizer     |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 13-Mar-2012  | 8408287        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2012037013 |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Anaesthesia; Injection Site Discolouration; Injury Associated With Device | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Mar-2012  | 8438398        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012045676 |                      | 18 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device  | Epipen         |                    |                    | S               |                          | .3 Mg, As Needed     |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Mar-2012  | 8428488        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2012045797 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device  | Epipen         |                    |                    | S               |                          | 0.3 Mg, Single       | 1 DAY           | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Mar-2012  | 8384247        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2012023029 |                      | 73 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cyanosis; Injury Associated With Device; Peripheral Coldness; Tremor   | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
|  | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 21-Mar-2012  | 8470507        | EXPEDITED (15-DAY) | Y                  | HO              | CH-PFIZER INC-2012071250 |                      | 8 YR            | Male       | CHE            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cyanosis; Drug Administration Error; Injection Site Pain   | Epipen Jr      |                    |                    | S               | Subcutaneous             | 15 Mg, 1x/Day Total  | 1 DAY           | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Mar-2012  | 8388739        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012027869 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Loss Of Personal Independence In Daily Activities                                | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Mar-2012  | 8472759        | EXPEDITED (15-DAY) | Y                  | OT              | AT-PFIZER INC-2012068000 |                      | 37 YR           | Male       | AUT            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Application Site Pallor; Bradycardia; Dizziness; Pain In Extremity; Pallor | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Mar-2012  | 8475387        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012073574 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 30-Mar-2012   | 8465258        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012067147 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia; Peripheral Coldness; Skin Discolouration | Epipen         |                    |                    | S               |                          | 0.3 Mg, Unk          | 365 DAY         | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2012   | 8478814        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012073367 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Skeletal Injury   | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Apr-2012   | 8475392        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2012073699 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Vasoconstriction  | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2012   | 8500962        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012085248 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Hypoaesthesia             | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Apr-2012   | 8503584        | EXPEDITED (15-DAY) | Y                  | OT              | JP-PFIZER INC-2012087213 |                      | 41 YR           | Male       | JPN            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Hypertension; Loss Of Consciousness   | Epipen         |                    |                    | S               | Intramuscular            | 0.3 Mg Daily         | 1 DAY           | Pfizer     |                |
|   | Claritin       |                    |                    | C               | Oral                     | 10 Mg, Qd            |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Apr-2012   | 8507247        | EXPEDITED (15-DAY) | N                  | HO              | GB-PFIZER INC-2012087170 |                      | 42 YR           | Female     | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Application Site Pain; Pain In Extremity                          | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2012   | 8486214        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2012079395 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Pain; Swelling   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Apr-2012   | 8449370        | NON-EXPEDITED      | Y                  |                 | US-PFIZER INC-2012056546 |                      | 71 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device; Ligament Injury; Pain In Extremity | Epipen         |                    |                    | S               | Intramuscular            |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Apr-2012   | 8486203        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2012079441 |                      | 54 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To  | Epipen Jr      |                    |                    | S               |                          |                      |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product; Expired Product  
Administered; Skin  
Discolouration; Swelling

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 01-May-2012              | 8492500       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2012077157 |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To<br>Product; Expired Product<br>Administered; Pain In<br>Extremity; Skin<br>Discolouration | Epipen         |              |            | S           |              |                    |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 02-May-2012              | 8234966       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2011261190 |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Application Site<br>Haematoma; Drug<br>Ineffective; Expired<br>Product Administered | Epipen<br>Twinject<br>Maxair |              |            | S<br>S<br>C |              | 0.3 Mg, Unk<br>Unk |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 02-May-2012              | 8521038       | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2012092630 |                      |            | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Application Site<br>Haematoma; Expired<br>Product Administered | Epipen<br>Twinject<br>Maxair |              |            | S<br>S<br>C |              | Unk<br>Unk<br>Unk  |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 07-May-2012              | 8518950       | NON-EXPEDITED    | Y                  |                 | US-PFIZER INC-<br>2012092413 |                      |            | Female     | USA            |

# FDA Adverse Event Reporting System

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product; Expired Product Administered; Pain In Extremity  | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-May-2012  | 8372110                 | NON-EXPEDITED             | N                           |                          | US-PFIZER INC-2012019541      |                               | 35 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Feeling Abnormal; Feeling Jittery                | Epipen Jr               |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-May-2012  | 8494993                 | NON-EXPEDITED             | N                           | OT                       | US-PFIZER INC-2012081547      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Dizziness; Hypoaesthesia                         | Epipen                  |                           |                             | S                        |                               | Unk                           | 1 DAY                    | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-May-2012  | 8497079                 | NON-EXPEDITED             | N                           |                          | US-PFIZER INC-2012082741      |                               | 32 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Contusion; Feeling Abnormal; Injection Site Pain | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-May-2012  | 8521035                 | NON-EXPEDITED             | Y                           |                          | US-PFIZER INC-2012094028      |                               | 17 YR                    | Female              | USA                     |

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| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Feeling Jittery; Heart Rate Increased; Hypertension; Pallor | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-May-2012   | 8554843        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012107676 |                      | 67 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Haemorrhage    | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-May-2012   | 8522978        | EXPEDITED (15-DAY) | N                  |                 | US-PFIZER INC-2012093900 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Pain In Extremity             | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-May-2012   | 8559850        | EXPEDITED (15-DAY) | N                  |                 | CA-PFIZER INC-2012112009 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-May-2012   | 8429959        | EXPEDITED (15-DAY) | N                  | HO              | US-JNJFOC-20120209139    |                      | 28 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                        |   |   |  |                                   |
|--|------------------------|---|---|--|-----------------------------------|
| Abnormal Loss Of Weight;<br>Body Height Decreased;<br>Cholelithiasis; Drug<br>Ineffective; Food Allergy;<br>Juvenile Idiopathic<br>Arthritis; Lipoma; Maternal<br>Exposure During<br>Pregnancy;<br>Nephrolithiasis; Tendon<br>Disorder | Remicade               |   | S | Intravenous (not<br>otherwise specified) |                                   |
|  | Remicade               |   | S | Intravenous (not<br>otherwise specified) | Also Reported As Every 6<br>Weeks |
|  | Remicade               |   | S | Intravenous (not<br>otherwise specified) |                                   |
|  | Morphine               |   | S | Unknown                                  |                                   |
|  | Fexofenadine           |   | S | Oral                                     |                                   |
|  | Imuran                 |   | S | Unknown                                  |                                   |
|  | Benadryl               | Y | S | Oral                                     |                                   |
|  | Epipen                 |   | S | Intramuscular                            |                                   |
|  | Solu-Medrol            |   | S | Unknown                                  |                                   |
|  | Benadryl               | Y | S | Unknown                                  |                                   |
|  | Calcium With Vitamin D |   | C | Oral                                     |                                   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-Jun-2012              | 8553822       | EXPEDITED (15-DAY) | Y                  | OT              | GB-PFIZER INC-<br>2012112110 |                      |            | Male       | GBR            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To<br>Product; Discomfort;<br>Expired Product<br>Administered; Injection<br>Site Discomfort | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 05-Jun-2012              | 8555862       | EXPEDITED (15-DAY) | Y                  | OT              | GB-PFIZER INC-<br>2012112084 |                      | 29 YR      | Female     | GBR            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Hypoaesthesia; Injection<br>Site Haematoma; Injury<br>Associated With Device | Epipen         |              |            | S           |              |                    |                 | Pfizer     |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 06-Jun-2012  | 8552687        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2012110925 |                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Injury Associated With Device; Peripheral Ischaemia | Epipen         |                    |                    | S               |                          | 0.3 Mg, Single       |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2012  | 8570253        | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2012118134 |                      | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Heart Rate Increased; Swelling             | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Jun-2012  | 8568667        | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-2012116574 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Jr      |                    |                    | S               |                          | Strength: 0.15 Mg    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Jun-2012  | 8580100        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2012123636 |                      | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Increased; Injury Associated With Device;                 | Epipen         |                    |                    | S               |                          | 0.3 Mg, Single       |                 | Pfizer     |                |

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Skin Discolouration;  
Tachycardia

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 21-Jun-2012              | 8627518        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2012126186 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event         | Epipen         |                  |                    | S               |                              | 0.3 Mg Unk           |                 | Pfizer     |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 03-Jul-2012                               | 8604183        | NON-EXPEDITED    | N                  |                 | US-PFIZER INC-<br>2012132415 |                      | 3 YR            | Female     | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Crying | Epipen         |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 06-Jul-2012  | 8576410        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-<br>2012122450 |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Hypoaesthesia;<br>Injection Site Pain;<br>Injection Site Pallor;<br>Muscular Weakness;<br>Neuralgia | Epipen         |                    |                    | S               | Intramuscular                | Unk                  | 1 DAY           | Pfizer     |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 11-Jul-2012  | 8559849        | EXPEDITED (15-DAY) | N                  | OT              | CA-PFIZER INC-<br>2012111189 |                      |                 | Male       | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Product Quality<br>Issue; Seizure | Epipen         |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|---------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 11-Jul-2012  | 8587238                         | NON-EXPEDITED             | Y                           |                          | US-PFIZER INC-2012127062      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective   | Epipen                          |                           |                             | S                        |                               | 0.3 Mg, Unk                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Jul-2012  | 8613794                         | NON-EXPEDITED             | N                           | OT                       | US-PFIZER INC-2012138439      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective   | Epipen                          |                           |                             | S                        |                               | 0.3 Mg, Unk                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Jul-2012  | 8492106                         | NON-EXPEDITED             | N                           | OT                       | US-JNJFOC-20120314657         |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dizziness; Drug Ineffective; Extrasystoles; Oedema Peripheral; Product Quality Issue | Benadryl                        |                           | Y                           | S                        | Oral                          |                               |                          |                     |                         |
|  | Zyrtec                          |                           | Y                           | S                        | Oral                          |                               |                          |                     |                         |
|  | Zyrtec                          |                           |                             | S                        | Oral                          | 11-12 Years                   |                          |                     |                         |
|  | Epipen                          |                           |                             | S                        | Unknown                       | 11-12 Years                   |                          |                     |                         |
|  | Unspecified Blood Pressure Meds |                           |                             | C                        | Unknown                       |                               |                          |                     |                         |
|  | All Other Therapeutic Products  |                           |                             | C                        | Unknown                       |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>          | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Jul-2012  | 8611242                         | EXPEDITED (15-DAY)        | N                           | OT                       | CA-PFIZER INC-2012136148      |                               | 15 YR                    | Female              | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>         | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaphylactic Reaction; Drug Ineffective; Product Quality Issue                       | Epipen                          |                           |                             | S                        |                               | Unk                           | 1 DAY                    | Pfizer              |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 19-Jul-2012   | 8621196        | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2012142520 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Poor Peripheral Circulation                                 | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Jul-2012   | 8632228        | EXPEDITED (15-DAY) | N                  | OT              | GB-PFIZER INC-2012150781 |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Heart Rate Increased; Loss Of Consciousness                 | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Aug-2012   | 8621214        | NON-EXPEDITED      | N                  | OT              | US-PFIZER INC-2012142542 |                      | 67 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Anaesthesia; Pallor                          | Epipen Jr      |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Aug-2012   | 8658854        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012162598 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Circumstance Or Information Capable Of Leading To Medication Error; Product Packaging Issue | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 03-Aug-2012   | 8660195                 | NON-EXPEDITED             | N                           |                          | US-PFIZER INC-2012163758      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pain  | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Aug-2012   | 8662554                 | NON-EXPEDITED             | N                           |                          | US-PFIZER INC-2012163790      |                               | 25 YR                    | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Pallor | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Aug-2012   | 8662572                 | NON-EXPEDITED             | N                           |                          | US-PFIZER INC-2012163788      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Therapeutic Response Unexpected                       | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Aug-2012   | 8704920                 | EXPEDITED (15-DAY)        | N                           | LT                       | GB-PFIZER INC-2012126190      |                               | 20 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Chest Pain; Device Failure                            | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Aug-2012   | 8662563                 | NON-EXPEDITED             | N                           |                          | US-PFIZER INC-2012163763      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                |                    |                    |                 |                          |                      |                 |            |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Injection Site Pain   |                | Epipen             |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Aug-2012   | 8660878        | EXPEDITED (15-DAY) | Y                  | HO              | GB-PFIZER INC-2012163564 |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Injury   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Aug-2012   | 8710714        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012174687 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2012   | 8679134        | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-2012172171 |                      | 23 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Discolouration; Pain | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Aug-2012   | 8714472        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012190432 |                      | 47 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 21-Aug-2012  | 8569593        | EXPEDITED (15-DAY) | N                  | HO              | GB-PFIZER INC-2012120164 |                      | 3 YR            | Female     | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion  | Epipen         |                    |                    | S               | Intramuscular            | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Aug-2012  | 8631248        | EXPEDITED (15-DAY) | Y                  | OT              | US-PFIZER INC-2012146250 |                      | 19 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective;<br>Pharyngeal Oedema   | Epipen         |                    |                    | S               |                          | 0.3 Mg, As Needed    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Aug-2012  | 8715134        | EXPEDITED (15-DAY) | N                  | OT              | US-PFIZER INC-2012190459 |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hand Fracture; Heart Rate Increased; Hypoaesthesia; Injection Site Pallor; Nail Bed Bleeding | Epipen         |                    |                    | S               | Intramuscular            | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Aug-2012  | 8734882        | NON-EXPEDITED      | N                  |                 | US-PFIZER INC-2012199682 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Circumstance Or Information Capable Of Leading To Medication Error; Drug Ineffective   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|--------------------------|------------------------------|-----------------|------------|----------------|
| 23-Aug-2012                                     | 8632513              | NON-EXPEDITED      | Y                  | OT              | US-PFIZER INC-2012148599 |                              | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Colour Issue          | Epipen               |                    |                    | S               | Intramuscular            | 0.3 Mg/0.3 MI, Prn           |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               |                          |                              |                 | Pfizer     |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Aug-2012                                     | 8750580              | DIRECT             | Y                  | OT              |                          |                              | 78 YR           | Female     | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction                              | Epipen               |                    |                    | S               |                          | 0.3ml As Needed By Injection |                 | Dey        |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Aug-2012                                     | 8729768              | EXPEDITED (15-DAY) |                    | OT              | NL-PFIZER INC-2012198492 |                              | 69 YR           | Male       | NLD            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Circulatory Collapse; Device Failure; Underdose | Epipen               |                    |                    | S               |                          | 1 Df, 1x/Day                 |                 | Pfizer     |                |
|   | Pariet               |                    |                    | C               |                          |                              |                 |            |                |
|   | Simvastatin          |                    |                    | C               |                          |                              |                 |            |                |
|   | Perindopril Erbumine |                    |                    | C               |                          | 4 Mg, 1x/Day                 |                 |            |                |
|   | Ascal Cardio         |                    |                    | C               | Oral                     | 100 Mg, 1x/Day               |                 |            |                |
|   | Metformin            |                    |                    | C               |                          | 500 Mg, 3x/Day               |                 |            |                |
|   | Alutard Sq "Alk"     |                    |                    | C               |                          | According To Scheme          |                 |            |                |
| <u>FDA Received Date</u>                        | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Sep-2012                                     | 8695683              | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012181556 |                              | 1 YR            | Male       | USA            |
| <u>Preferred Term</u>                           | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |



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|   |                |                    |                    |                 |                              |                      |                 |            |                |
|---|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| Injection Site Bruising;<br>Injection Site Injury;<br>Injection Site Pain;<br>Product Quality Issue |                | Epipen Jr          |                    | S               |                              |                      | Unk             |            | Pfizer         |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Sep-2012   | 8702522        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2012183966 |                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injection Site<br>Discolouration                                 | Epipen         |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2012   | 8721391        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2012195876 |                      | 41 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Hypoaesthesia;<br>Pain In Extremity                              | Epipen         |                    |                    | S               |                              | Unk %, Unk           |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2012   | 8762865        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-<br>2012210053 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error;<br>Drug Ineffective;<br>Dyspnoea   | Epipen         |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2012   | 8763990        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2012211332 |                      | 79 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Blood Pressure   | Epipen Jr      |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |

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Increased; Tachycardia

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------------|-----------------|------------|----------------|
| 10-Sep-2012  | 8721733        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012192214 |                            | 91 DAY          | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Haemorrhage                                   | Epipen         |                    |                    | S               |                          | Unk                        |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Sep-2012  | 8713951        | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2012186859 |                            | 5 YR            | Male       | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Product Quality Issue   | Epipen         |                    |                    | S               |                          | Unk                        |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Sep-2012  | 8790451        | DIRECT             |                    | HO              |                          |                            | 42 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device; Product Label Issue; Wrong Technique In Product Usage Process | Epipen         |                    |                    | S               |                          | Expiration Date 10/31/2010 |                 | Dey        |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Sep-2012  | 8778738        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012197263 |                            |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event   | Epipen         |                    |                    | S               |                          | Unk                        |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 19-Sep-2012                             | 8726428        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2012195892 |                      | 67 YR           | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Quality Issue | Epipen         |                  |                    | S               |                          | 0.3 Mg/MI            |                 | Pfizer     |                |
|   | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Sep-2012                             | 8731238        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2012197252 |                      | 14 YR           | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Quality Issue | Epipen         |                  |                    | S               | Intramuscular            | 0.3 MI, As Needed    |                 | Pfizer     |                |
|   | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |
|   | Accolate       |                  |                    | C               | Oral                     | Unk                  |                 |            |                |
|   | Dulera         |                  |                    | C               | Nasal                    | Unk                  |                 |            |                |
|   | Qvar           |                  |                    | C               | Nasal                    | Unk                  |                 |            |                |
|   | Ventolin       |                  |                    | C               | Nasal                    | Unk                  |                 |            |                |
| <u>FDA Received Date</u>                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Sep-2012                             | 8676361        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2012172076 |                      | 31 YR           | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Needle Issue          | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Buspirone      |                  |                    | C               | Oral                     | 5 Mg, 3x/Day         |                 |            |                |
|   | Buspirone      |                  |                    | C               |                          |                      |                 |            |                |
|   | Fluoxetine     |                  |                    | C               | Oral                     | 40 Mg, 2x/Day        |                 |            |                |
|   | Fluoxetine     |                  |                    | C               |                          |                      |                 |            |                |
|   | Metformin      |                  |                    | C               | Oral                     | 500 Mg, 2x/Day       |                 |            |                |
|   | Ambien         |                  |                    | C               | Oral                     | 10 Mg, 1x/Day        |                 |            |                |
|   | Zonisamide     |                  |                    | C               | Oral                     | 100 Mg, 1x/Day       |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|           |   |      |        |
|-----------|---|------|--------|
| Calcium   | C | Oral | Unk Qd |
| Magnesium | C | Oral | Unk Qd |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2012              | 8725471       | EXPEDITED (15-DAY) |                    | HO              | US-PFIZER INC-2012198571 |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |
|-----------------------------|----------------|--------------|------------|-------------|---------------------------------------|--------------------------|-----------------|------------|
| Acute Myocardial Infarction | Epipen         |              |            | S           | Intramuscular                         | 0.3 Mg, Single           |                 | Pfizer     |
|                             | Solu-Medrol    |              |            | C           | Intravenous (not otherwise specified) | 125 Mg, Single           |                 |            |
|                             | Zofran         |              |            | C           | Intravenous (not otherwise specified) | 4 Mg, Single             |                 |            |
|                             | Benadryl       |              |            | C           | Intravenous (not otherwise specified) | 50 Mg, Single            |                 |            |
|                             | Ativan         |              |            | C           | Intravenous (not otherwise specified) | 1 Mg, Single             |                 |            |
|                             | Zantac         |              |            | C           | Intravenous (not otherwise specified) | 50 Mg, Single            |                 |            |
|                             | Combivent      |              |            | C           | Respiratory (inhalation)              | Two Nebuliser Treatments |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 26-Sep-2012              | 8761379       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012207673 |                      | 2 YR       | Male       | USA            |

| <u>Preferred Term</u>                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Crying; Injury Associated With Device; Pain | Epipen Jr      |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 27-Sep-2012              | 8762641       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2012206273 |                      |            | Female     | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Musculoskeletal Stiffness | Epipen         |              |            | S           |              |                    |                 | Pfizer     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-------------------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 28-Sep-2012  | 8738724                 | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012203447   |                      | 36 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Contusion; Hypoaesthesia; Pain | Epipen                  |                    |                    | S               |                            | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Sep-2012  | 8815122                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012240473   |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event   | Epipen                  |                    |                    | S               |                            | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Oct-2012  | 8821743                 | EXPEDITED (15-DAY) |                    | OT              | US-009507513-1210USA000708 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Condition Aggravated; Memory Impairment; Myocardial Infarction | Janumet                 |                    |                    | S               | Oral                       | 50mg/500mg,Qd        |                 | Merck      |                |
|  | Zocor                   |                    |                    | S               | Oral                       |                      |                 | Merck      |                |
|  | Diovan                  |                    |                    | S               | Oral                       | 160 Mg, Qd           |                 |            |                |
|  | Metformin               |                    |                    | S               | Oral                       | 500 Mg, Qd           |                 |            |                |
|  | Nitrolingual            |                    |                    | S               |                            | 0.4 Mg, Prn          |                 |            |                |
|  | Zyrtec                  |                    |                    | S               | Oral                       | 10 Mg, Qd            |                 |            |                |
|  | Gabapentin              |                    |                    | S               | Oral                       | 2 Df, Tid            |                 |            |                |
|  | Vicodin                 |                    |                    | S               | Oral                       | 1 Df, Q4h            |                 |            |                |
|  | Bupropion Hydrochloride |                    |                    | S               | Oral                       | 300 Mg, Qd           |                 |            |                |
|  | Lozol                   |                    |                    | S               | Oral                       | 1.5 Mg, Qd           |                 |            |                |
|  | Klonopin                |                    |                    | S               | Oral                       | 0.5 Mg, Bid          |                 |            |                |
|  | Prilosec                |                    |                    | S               | Oral                       | 20 Mg, Bid           |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |             |             |
|---------------------------------|---|-------------|-------------|
| Carafate                        | S | Oral        | 1 G, Bid    |
| Aggrenox                        | S | Oral        | Unk, Bid    |
| Flonase                         | S | Nasal       | 4 Df, Qd    |
| Flovent                         | S |             | 2 Df, Bid   |
| Ventolin (Albuterol)            | S |             | 2 Df, Q2h   |
| Imitrex (Sumatriptan Succinate) | S | Oral        | 100 Mg, Prn |
| Epipen                          | S | Transdermal |             |
| Lortab                          | S | Oral        |             |
| Vitamins (Unspecified)          | S |             |             |
| Zanaflex                        | S | Oral        | 2 Mg, Bid   |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 02-Oct-2012              | 8821756       | EXPEDITED (15-DAY) |                    | OT              | US-MERCK-1210USA000465 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                    | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|-------------------------|--------------|------------|-------------|--------------------------|--------------------|-----------------|------------|
| Anxiety; Arterial Disorder;              | Janumet                 |              |            | S           | Oral                     |                    |                 | Merck      |
| Arthralgia; Asthma;                      | Zocor                   |              |            | S           | Oral                     |                    |                 | Merck      |
| Cardiac Disorder;                        | Aggrenox                |              |            | S           | Oral                     |                    |                 |            |
| Condition Aggravated;                    | Gabapentin              |              |            | S           | Oral                     |                    |                 |            |
| Depression; Diabetes Mellitus; Diabetic  | Vicodin                 |              |            | S           | Oral                     |                    |                 |            |
| Neuropathy; Fibromyalgia;                | Zanaflex                |              |            | S           | Oral                     | 4 Mg, Unk          |                 |            |
| Gastrooesophageal Reflux Disease; Memory | Valsartan               |              |            | S           | Oral                     | 160 Mg, Unk        |                 |            |
| Impairment; Muscle Spasms; Panic Attack  | Bupropion Hydrochloride |              |            | S           | Oral                     | 300 Mg, Unk        |                 |            |
|  | Lozol                   |              |            | S           | Oral                     | 1.25 Mg, Unk       |                 |            |
|  | Metformin               |              |            | S           | Oral                     | 500 Mg, Unk        |                 |            |
|  | Klonopin                |              |            | S           | Oral                     | 1 Mg, Unk          |                 |            |
|  | Prilosec                |              |            | S           | Oral                     | 40 Mg, Unk         |                 |            |
|  | Carafate                |              |            | S           | Oral                     | 2 G, Unk           |                 |            |
|  | Flonase                 |              |            | S           | Respiratory (inhalation) |                    |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                 |   |             |                    |
|---------------------------------|---|-------------|--------------------|
| Flovent                         | S |             | 440 Microgram, Unk |
| Ventolin (Albuterol Sulfate)    | S |             |                    |
| Imitrex (Sumatriptan Succinate) | S | Oral        |                    |
| Nitrolingual                    | S |             |                    |
| Epipen                          | S | Transdermal |                    |
| Lortab                          | S | Oral        |                    |
| Vitamins (Unspecified)          | S | Oral        |                    |
| Zyrtec                          | S | Oral        | 10 Mg, Unk         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>   | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------|----------------------|------------|------------|----------------|
| 03-Oct-2012              | 8823483       | EXPEDITED (15-DAY) |                    | OT              | US-MERCK-1210USA000868 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>               | <u>Product</u>                  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------|---------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Cardiac Disorder; Memory Impairment | Januvia                         |              |            | S           | Oral         |                    |                 | Merck      |
|                                     | Bupropion Hydrochloride         |              |            | S           | Oral         | 300 Mg, Qd         |                 |            |
|                                     | Vitamins (Unspecified)          |              |            | S           | Oral         |                    |                 |            |
|                                     | Gabapentin                      |              |            | S           | Oral         | 2 Df, Tid          |                 |            |
|                                     | Vicodin                         |              |            | S           | Oral         |                    |                 |            |
|                                     | Zanaflex                        |              |            | S           | Oral         | 2 Mg, Bid          |                 |            |
|                                     | Diovan                          |              |            | S           | Oral         | 160 Mg, Qd         |                 |            |
|                                     | Lozol                           |              |            | S           | Oral         | 1.25 Mg, Qd        |                 |            |
|                                     | Metformin                       |              |            | S           | Oral         | 500 Mg, Qd         |                 |            |
|                                     | Klonopin                        |              |            | S           | Oral         | 0.5 Mg, Bid        |                 |            |
|                                     | Prilosec                        |              |            | S           | Oral         | 20 Mg, Bid         |                 |            |
|                                     | Carafate                        |              |            | S           |              | 1 G, Bid           |                 |            |
|                                     | Aggrenox                        |              |            | S           | Oral         |                    |                 |            |
|                                     | Flonase                         |              |            | S           | Nasal        | 50 Microgram, Bid  |                 |            |
|                                     | Flovent                         |              |            | S           | Nasal        | 110 Microgram, Bid |                 |            |
|                                     | Ventolin (Albuterol Sulfate)    |              |            | S           | Nasal        |                    |                 |            |
|                                     | Imitrex (Sumatriptan Succinate) |              |            | S           | Oral         | 100 Mg, Prn        |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|              |   |             |             |
|--------------|---|-------------|-------------|
| Nitrolingual | S | Sublingual  | 0.4 Mg, Prn |
| Epipen       | S | Transdermal |             |
| Simvastatin  | S | Oral        |             |
| Zyrtec       | S | Oral        | 10 Mg, Qd   |
| Lortab       | S | Oral        |             |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 03-Oct-2012              | 8823861       | EXPEDITED (15-DAY) |                    | OT              | US-009507513-1210USA000559 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|-------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Condition Aggravated;<br>Feeling Abnormal;<br>Memory Impairment | Janumet                 |              |            | S           |              | 50/500, Qd         |                 | Merck      |
|   | Carafate                |              |            | S           | Oral         | 1 G, Qd            |                 |            |
|   | Lozol                   |              |            | S           | Oral         | 1.25 Mg, Qd        |                 |            |
|   | Zyrtec                  |              |            | S           |              | 10 Mg, Qd          |                 |            |
|   | Gabapentin              |              |            | S           |              |                    |                 |            |
|   | Vicodin                 |              |            | S           |              | 7.5mg/325mg, Q4h   |                 |            |
|   | Zanaflex                |              |            | S           |              | 2 Mg, Bid          |                 |            |
|   | Valsartan               |              |            | S           |              | 160 Mg, Qd         |                 |            |
|   | Bupropion Hydrochloride |              |            | S           |              | 300 Mg, Qd         |                 |            |
|   | Metformin               |              |            | S           |              | 500 Mg, Qd         |                 |            |
|   | Klonopin                |              |            | S           |              | 0.5 Mg, Bid        |                 |            |
|   | Prilosec                |              |            | S           |              |                    |                 |            |
|   | Aggrenox                |              |            | S           |              |                    |                 |            |
|   | Flonase                 |              |            | S           | Nasal        | 50 Microgram, Unk  |                 |            |
|   | Flovent                 |              |            | S           |              | 220 Microgram, Bid |                 |            |
|   | Ventolin (Albuterol)    |              |            | S           |              |                    |                 |            |
|   | Imitrex (Sumatriptan)   |              |            | S           |              | 100 Mg, Prn        |                 |            |
|   | Nitrolingual            |              |            | S           |              | 0.4 Mg, Prn        |                 |            |
|   | Epipen                  |              |            | S           | Transdermal  |                    |                 |            |
|   | Lortab                  |              |            | S           | Oral         |                    |                 |            |
| Zocor   |                         |              | S          |             |              |                    | Merck           |            |



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Vitamins (Unspecified)  
Flexeril

S  
C

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 03-Oct-2012              | 8824014       | EXPEDITED (15-DAY) |                    | OT              | US-009507513-<br>1210USA000836 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                       | <u>Product</u>          | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|---|-------------------------|--------------|------------|-------------|-----------------------------|------------------------|-----------------|------------|
| Memory Impairment;<br>Myocardial Infarction | Janumet                 |              |            | S           | Oral                        | Unk                    |                 | Merck      |
|   | Zocor                   |              |            | S           | Oral                        |                        |                 | Merck      |
|   | Klonopin                |              |            | S           | Oral                        |                        |                 |            |
|   | Zyrtec                  |              |            | S           | Oral                        |                        |                 |            |
|   | Gabapentin              |              |            | S           | Oral                        | Unk                    |                 |            |
|   | Vicodin                 |              |            | S           | Oral                        |                        |                 |            |
|   | Zanaflex                |              |            | S           | Oral                        |                        |                 |            |
|   | Valsartan               |              |            | S           | Oral                        |                        |                 |            |
|   | Bupropion Hydrochloride |              |            | S           | Oral                        |                        |                 |            |
|   | Lozol                   |              |            | S           | Oral                        | Pill                   |                 |            |
|   | Prilosec                |              |            | S           | Oral                        |                        |                 |            |
|   | Carafate                |              |            | S           | Oral                        |                        |                 |            |
|   | Aggrenox                |              |            | S           | Oral                        |                        |                 |            |
|   | Flonase                 |              |            | S           | Respiratory<br>(inhalation) | Two Sprays Per Nostril |                 |            |
|   | Flovent                 |              |            | S           | Unknown                     | Two Puffs, Bid         |                 |            |
|   | Ventolin (Albuterol)    |              |            | S           | Unknown                     | Two Puffs, Q2h         |                 |            |
|   | Imitrex (Sumatriptan)   |              |            | S           | Oral                        |                        |                 |            |
|   | Nitrolingual            |              |            | S           | Unknown                     | Spray                  |                 |            |
|   | Epipen                  |              |            | S           | Transdermal                 |                        |                 |            |
|   | Lortab                  |              |            | S           | Oral                        |                        |                 |            |
|   | Metformin               |              |            | S           | Oral                        |                        |                 |            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> |             | <u>Outcomes</u>          | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|-------------------------|--------------------|--------------------|-------------|--------------------------|----------------------------|----------------------|-----------------|------------|----------------|
| 03-Oct-2012   | 8824080                 | EXPEDITED (15-DAY) |                    |             | OT                       | US-009507513-1210USA000791 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u>         |                      | <u>Duration</u> |            | <u>Mfr</u>     |
| Anxiety; Arterial Disorder; Arthralgia; Asthma; Cardiac Disorder; Chest Pain; Depression; Diabetic Neuropathy; Fibromyalgia; Gastrooesophageal Reflux Disease; Memory Impairment; Migraine; Multiple Allergies; Muscle Spasms; Panic Attack | Janumet                 |                    |                    | S           |                          | 500/50 Mg, Qd              |                      |                 |            | Merck          |
|   | Zanaflex                |                    |                    | S           | Oral                     | 2 Mg, Bid                  |                      |                 |            |                |
|   | Gabapentin              |                    |                    | S           | Oral                     | 2 Df, Tid                  |                      |                 |            |                |
|   | Vicodin                 |                    |                    | S           | Oral                     | 7.5 Mg/325 Mg, Q4h         |                      |                 |            |                |
|   | Valsartan               |                    |                    | S           | Oral                     | 160 Mg, Qd                 |                      |                 |            |                |
|   | Bupropion Hydrochloride |                    |                    | S           | Oral                     | 300 Mg, Qd                 |                      |                 |            |                |
|   | Lozol                   |                    |                    | S           | Oral                     | 1.25 Mg, Qd                |                      |                 |            |                |
|   | Metformin               |                    |                    | S           | Oral                     | 500 Mg, Qd                 |                      |                 |            |                |
|   | Klonopin                |                    |                    | S           | Oral                     | 0.5 Mg, Bid                |                      |                 |            |                |
|   | Prilosec                |                    |                    | S           | Oral                     | 20 Mg, Bid                 |                      |                 |            |                |
|   | Carafate                |                    |                    | S           | Oral                     | 1 G, Bid                   |                      |                 |            |                |
|   | Aggrenox                |                    |                    | S           | Oral                     | Unk, Bid                   |                      |                 |            |                |
|   | Flonase                 |                    |                    | S           | Nasal                    | 4 Df, Qd                   |                      |                 |            |                |
|   | Flovent                 |                    |                    | S           | Respiratory (inhalation) | 2 Df, Bid                  |                      |                 |            |                |
|   | Ventolin (Albuterol)    |                    |                    | S           | Respiratory (inhalation) | 2 Df, Q2h                  |                      |                 |            |                |
|   | Imitrex (Sumatriptan)   |                    |                    | S           | Oral                     | 100 Mg, Prn                |                      |                 |            |                |
|   | Nitrolingual            |                    |                    | S           |                          | 1 Df, Prn                  |                      |                 |            |                |
|   | Epipen                  |                    |                    | S           | Intramuscular            |                            |                      |                 |            |                |
|   | Lortab                  |                    |                    | S           | Oral                     | Unk Df, Unk                |                      |                 |            |                |
|   | Zocor                   |                    |                    | S           | Oral                     | Unk Df, Unk                |                      |                 |            | Merck          |
|   | Vitamins (Unspecified)  |                    |                    | S           | Oral                     | Unk Df, Unk                |                      |                 |            |                |
|   | Zyrtec                  |                    |                    | S           | Oral                     | 10 Mg, Qd                  |                      |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|----------------------------|-------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 04-Oct-2012                | 8817399                 | EXPEDITED (15-DAY) |                    | DE              | SK-PFIZER INC-2012246113 |                      | 61 YR           | Male       | SVK            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death                      | Epipen                  |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|                            | Rytmonorm               |                    |                    | C               | Oral                     | 450 Mg, 1 In 1 D     |                 |            |                |
|                            | Gopten "Abbott"         |                    |                    | C               | Oral                     | 2 Mg, 1 In 1 D       |                 |            |                |
|                            | Anopyrin                |                    |                    | C               | Oral                     | 100 Mg, 1 In 1 D     |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Oct-2012                | 8828625                 | EXPEDITED (15-DAY) |                    | OT              | SK-PFIZER INC-2012246405 |                      | 61 YR           | Male       | SVK            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Tachycardia                | Epipen                  |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|                            | Rytmonorm               |                    |                    | C               | Oral                     | 450 Mg, 1 In 1 D     |                 |            |                |
|                            | Gopten "Abbott"         |                    |                    | C               | Oral                     | 2 Mg, 1 In 1 D       |                 |            |                |
|                            | Anopyrin                |                    |                    | C               | Oral                     | 100 Mg, 1 In 1 D     |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Oct-2012                | 8837037                 | EXPEDITED (15-DAY) |                    | OT              | CHPA2012US021051         |                      | 61 YR           | Female     | USA            |
| <u>Preferred Term</u>      | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction;     | Excedrin Extra Strength |                    | Y                  | S               | Oral                     | 1-2 Df, Prn          |                 | Novartis   |                |
| Chills; Ear Pain;          | Epipen                  |                    |                    | S               |                          | Unk, Unk             |                 |            |                |
| Headache; Hot Flush;       |                         |                    |                    |                 |                          |                      |                 |            |                |
| Nasopharyngitis;           |                         |                    |                    |                 |                          |                      |                 |            |                |
| Oropharyngeal Pain; Pain;  |                         |                    |                    |                 |                          |                      |                 |            |                |
| Premature Menopause;       |                         |                    |                    |                 |                          |                      |                 |            |                |
| Product Use In             |                         |                    |                    |                 |                          |                      |                 |            |                |
| Unapproved Indication;     |                         |                    |                    |                 |                          |                      |                 |            |                |
| Sinusitis; Underdose;      |                         |                    |                    |                 |                          |                      |                 |            |                |
| Urticaria; Viral Infection |                         |                    |                    |                 |                          |                      |                 |            |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2012   | 8671838        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2012166683 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                    |                    | S               |                          | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2012   | 8640393        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012150548 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cold Sweat; Nausea  | Epipen         |                    |                    | S               |                          | 0.3mg, Unk           |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Oct-2012   | 8797305        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012226967 |                      | 66 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Chest Discomfort; Injection Site Discolouration | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Oct-2012   | 8801950        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012232285 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Apnoea  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Oct-2012   | 8814440        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012238235 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|   |                |                    |                    |                 |                          |                      |                 |            |                |

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|   |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Drug Ineffective; Loss Of Consciousness                           |                         | Epipen                    | S                           |                          | Unk                           |                               | Pfizer                   |                     |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Oct-2012   | 8822197                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2012240475      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Bruising; Injection Site Haemorrhage               | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Oct-2012   | 8778070                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2012220103      |                               | 2 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Pain   | Epipen Jr               |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
|   | Epipen Jr               |                           |                             | S                        |                               |                               |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Oct-2012   | 8769394                 | EXPEDITED (15-DAY)        |                             | OT                       | GB-PFIZER INC-2012217353      |                               |                          | Female              | GBR                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Contusion; Limb Discomfort  | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Oct-2012   | 8702525                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2012185320      |                               | 82 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Injury; Injection Site Pain; Product Quality Issue | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once In Left Thigh    |                          | Pfizer              |                         |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 23-Oct-2012  | 8780582        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012221110 |                      | 24 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; Injection Site Pain   | Epipen         |                    |                    | S               | Intramuscular            | 1 Dose As Needed     |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Oct-2012  | 8829946        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012244852 |                      | 23 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Bone Pain; Drug Administration Error; Myalgia  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Oct-2012  | 8850451        | EXPEDITED (15-DAY) |                    | DE              | GB-PFIZER INC-2012251710 |                      | 11 YR           | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death; Drug Ineffective  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Oct-2012  | 8392484        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012027784 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Feeling Jittery; Injection Site Pain; Injury Associated With Device; Nervousness; Tachyphrenia | Epipen Jr      |                    |                    | S               |                          | 0.15 Mg, Unk         |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 29-Oct-2012  | 8838196        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012251824 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Haemorrhage   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Oct-2012  | 8851767        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012257702 |                      | 28 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Dizziness; Hyperventilation                                      | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Nov-2012  | 8861314        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012266674 |                      | 61 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pallor  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Nov-2012  | 8873181        | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2012266475 |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Heart Rate Increased; Hypertension | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 09-Nov-2012  | 8762644                 | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2012211442      |                               | 57 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Product Quality Issue                    | Epipen                  |                           |                             | S                        |                               | 0.3 Mg, As Needed             |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Nov-2012  | 8915347                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2012282858      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Insomnia; Mood Altered                                     | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
|  | Benadryl                |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Nov-2012  | 8915473                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2012284209      |                               | 14 YR                    | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Haemorrhage | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Nov-2012  | 8932551                 | EXPEDITED (15-DAY)        | Y                           | HO, OT                   | THQ2012A10141                 |                               | 61 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Wrong Technique In Product Usage Process   | Lansoprazole            |                           |                             | S                        |                               | 30 Mg (30 Mg, 1-1 D)          |                          |                     |                         |
|  | Epipen                  |                           |                             | S                        |                               |                               | 30 DAY                   |                     |                         |
|  | Etoricoxib              |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Nov-2012  | 8928683                 | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-PFIZER INC-                |                               | 48 YR                    | Male                | USA                     |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2012292562

| <u>Preferred Term</u>   | <u>Product</u>     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |
|---|--------------------|--------------|------------|-------------|--------------|--------------------------|-----------------|------------|
| Accidental Exposure To Product; Anaphylactic Shock; Brain Death | Epipen<br>Benadryl |              |            | S<br>C      |              | Two Epipens<br>Two Doses |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 04-Dec-2012              | 8913091       | EXPEDITED (15-DAY) |                    | HO              | GR-PFIZER INC-2012244834 |                      |            | Female     | GRC            |

| <u>Preferred Term</u>                                      | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Electrocardiogram Abnormal | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Dec-2012              | 8875092       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2012268062 |                      | 46 YR      | Male       | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Product Quality Issue | Epipen         |              |            | S           |              | 0.3 Mg, Unk        |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Dec-2012              | 8960564       | DIRECT           |                    | LT              |                      |                      | 48 YR      | Male       | USA            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Ineffective; Wrong Device Used | Epipen         |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 10-Dec-2012              | 8895349       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012277566 |                      | 8 YR       | Male       | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Abdominal Pain Upper;<br>Dizziness; Sinusitis; Vision<br>Blurred | Epipen         |              |            | S           | Unknown      | Unk                |                 | Pfizer     |
|  | Benadryl       |              |            | C           |              | Unk                |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2012              | 8960264       | EXPEDITED (15-DAY) |                    | OT              | US-009507513-<br>1212USA003236 |                      | 55 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>               | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                     | <u>Duration</u> | <u>Mfr</u> |
|---|------------------------------|--------------|------------|-------------|--------------|--|-----------------|------------|
| Arterial Disorder; Ill-<br>Defined Disorder; Memory<br>Impairment | Simvastatin Tablets, Usp     |              |            | S           | Oral         | Unk                                    |                 | Merck      |
|   | Janumet                      |              |            | S           | Oral         | 50/500 Mg, Qd                          |                 | Merck      |
|   | Prilosec                     |              |            | S           | Oral         | 20 Mg, Bid                             |                 | Merck      |
|   | Gabapentin                   |              |            | S           | Oral         | 2 Df, Tid                              |                 |            |
|   | Gabapentin                   |              |            | S           |              |  |                 |            |
|   | Metformin                    |              |            | S           | Oral         | 500 Mg, Qd                             |                 |            |
|   | Zyrtec                       |              |            | S           | Oral         | 10 Mg, Qd                              |                 |            |
|   | Vicodin                      |              |            | S           | Oral         | 7.5/325 Mg, Q4h                        |                 |            |
|   | Zanaflex                     |              |            | S           | Oral         | 2 Mg, Bid                              |                 |            |
|   | Valsartan                    |              |            | S           | Oral         | 160 Mg, Qd                             |                 |            |
|   | Bupropion Hydrochloride      |              |            | S           | Oral         | 300 Mg, Qd                             |                 |            |
|   | Lozol                        |              |            | S           | Oral         | 1.25 Mg, Qd                            |                 |            |
|   | Klonopin                     |              |            | S           | Oral         | 0.5 Mg, Bid                            |                 |            |
|   | Klonopin                     |              |            | S           |              |  |                 |            |
|   | Carafate                     |              |            | S           | Oral         | 1 G, Bid                               |                 |            |
|   | Aggrenox                     |              |            | S           | Oral         | Unk, Bid                               |                 |            |
|   | Flonase                      |              |            | S           | Nasal        | 500 Mcg, 2 Sprays Daily<br>Per Nostril |                 |            |
|   | Flovent                      |              |            | S           |              | 110 Mg Per Puff, 2 Puffs<br>Bid        |                 |            |
|   | Ventolin (Albuterol Sulfate) |              |            | S           | Oral         | 90 Mcg Per Puff, 2 Puffs<br>Q2h        |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                        |   |             |             |
|------------------------|---|-------------|-------------|
| Imitrex (Sumatriptan)  | S | Oral        | 100 Mg, Prn |
| Nitrolingual           | S | Oral        | 0.4 Mg, Prn |
| Epipen                 | S | Transdermal | Unk         |
| Lortab                 | S | Oral        |             |
| Vitamins (Unspecified) | S | Oral        | Unk         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 17-Dec-2012              | 8926702       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2012291062 |                      |            | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Expired Product Administered; Head Discomfort; Injection Site Bruising; Nervousness; Pain In Extremity; Paraesthesia; Peripheral Swelling; Skin Discolouration; Somnolence | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Dec-2012              | 8920127       | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2012287934 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective      | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 20-Dec-2012              | 8928847       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2012292557 |                      | 50 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Contusion; Product Quality Issue | Epipen Jr      |              |            | S           |              | Unk                |                 | Pfizer     |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 20-Dec-2012   | 8978035        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2012318433 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Swollen Tongue  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Benadryl       |                    |                    | S               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Dec-2012   | 8990157        | EXPEDITED (15-DAY) |                    | DE              | JP-PFIZER INC-2012330312 |                      | 11 YR           | Female     | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                    |                    | S               | Intramuscular            | Unk                  |                 | Pfizer     |                |
|   | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Dec-2012   | 8990725        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012327965 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Jan-2013   | 8993464        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012330958 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Rate Increased  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Jan-2013   | 8917180        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2012286586 |                      | 40 YR           | Female     | USA            |

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| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective                                    | Epipen         |                    |                    | S               |                          | 1 Df, As Needed      |                 | Pfizer     |                |
|   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Jan-2013   | 9132260        | EXPEDITED (15-DAY) |                    | HO              | BE-PFIZER INC-2013006961 |                      | 5 YR            | Unknown    | BEL            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Application Site Pain; Tachycardia                  | Epipen         |                    |                    | S               | Cutaneous                | 1 In 1 Total         |                 | Pfizer     |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Jan-2013   | 9011364        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013004511 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Jan-2013   | 9005942        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013007139 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Insomnia  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Jan-2013   | 9005983        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012256608 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event                                    | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 16-Jan-2013  | 8919592        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2012289496 |                      | 9 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Cough; Dyspnoea                                  | Epipen Jr      |                    |                    | S               |                          | 0.15 Mg, As Needed   |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jan-2013  | 9123829        | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-2013016551 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Aspiration; Brain Hypoxia; Cardiac Arrest; Incorrect Dose Administered; Vomiting | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jan-2013  | 9123940        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013016549 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Feeling Jittery                                  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jan-2013  | 8773767        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012220213 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Jan-2013  | 8947977        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2012300213 |                      |                 | Male       | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Jan-2013   | 9033103        | EXPEDITED (15-DAY) |                    | HO              | US-PFIZER INC-2013030461 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Chest Pain; Drug Ineffective; Dyspnoea; Neck Pain; Vomiting   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Benadryl       |                    |                    | S               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Feb-2013   | 9006433        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013007251 |                      | 33 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Increased; Heart Rate Increased; Injection Site Injury | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Feb-2013   | 9017325        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013018337 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Feb-2013   | 9023924        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013020304 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product   | Epipen         |                    |                    | S               |                          | 0.3 Mg, Prn          |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Administered;  
Hypoaesthesia;  
Palpitations; Peripheral  
Coldness

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 07-Feb-2013  | 9052358        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013033682 |                      | 4 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injection Site<br>Haemorrhage; Injection<br>Site Injury; Injection Site<br>Pain | Epipen Jr      |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Feb-2013  | 8970910        | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-<br>2012314964 |                      | 30 YR           | Unknown    | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Pain In Extremity;<br>Skin Discolouration                                       | Epipen         |                    |                    | S               | Unknown                      | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Feb-2013  | 9097905        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-<br>2013052743 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Dizziness   | Epipen Jr      |                    |                    | S               |                              | 0.15 Mg              |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Feb-2013  | 9012502        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013014323 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                |                    |                    |                 |                          |                       |                 |            |                |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|-----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Anxiety; Flushing; Palpitations; Product Quality Issue |                | Epipen<br>Motrin   |                    | S<br>C          | Subcutaneous             | 0.3 Mg, Single<br>Unk |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2013  | 9082001        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013052784 |                       | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Contusion; Peripheral Swelling                         | Epipen Jr      |                    |                    | S               |                          | Unk                   |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Feb-2013  | 9116981        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013027980 |                       |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event   | Epipen         |                    |                    | S               |                          | Unk                   |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Feb-2013  | 9148714        | DIRECT             |                    | OT              |                          |                       | 54 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction   | Epipen         |                    |                    | S               |                          | One Shot              |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Mar-2013  | 9134951        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013070894 |                       |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Loss Of Consciousness                                  | Epipen         |                    |                    | S               |                          | Unk                   |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---------------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------|-----------------|------------|----------------|
| 06-Mar-2013   | 9109809                         | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013064943 |                           |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Injury     | Epipen                          |                    |                    | S               | Unknown                  | Unk                       |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Mar-2013   | 9100360                         | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2013060288 |                           | 2 YR            | Male       | GBR            |
| <u>Preferred Term</u>                                     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Device Difficult To Use; Laceration; Psychological Trauma | Epipen Jr<br>Piriton            |                    |                    | S<br>C          | Intramuscular<br>Oral    | 1 Df, 1 In 1 Total<br>Unk |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Mar-2013   | 9147811                         | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2013077506 |                           | 50 YR           | Female     | GBR            |
| <u>Preferred Term</u>                                     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Hypersensitivity  | Epipen<br>Salbutamol<br>Victoza |                    |                    | S<br>C<br>C     | Intramuscular            | 0.5 Mg, Unk<br>Unk<br>Unk |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Mar-2013   | 9147240                         | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013076019 |                           |                 | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Heart Rate Increased            | Epipen                          |                    |                    | S               |                          | Unk                       |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 13-Mar-2013  | 8998996        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012330989 |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Product Quality Issue | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|  | Aleve          |                    |                    | C               |                          | Prn (As Needed)      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Mar-2013  | 9159879        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013080481 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Haemorrhage; Sedation  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Mar-2013  | 9154302        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013080476 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Mar-2013  | 9159724        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013080483 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Euphoric Mood  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|  | Benadryl       |                    |                    | S               |                          | 2 Shots              |                 |            |                |
|  | Zantac         |                    |                    | S               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Apr-2013  | 9213121        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013102995 |                      |                 | Female     | USA            |

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| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Heart Rate Increased | Epipen         |                  |                    | S               |                          | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Apr-2013  | 9216640        | NON-EXPEDITED    |                    | HO, OT          | US-PFIZER INC-2013105378 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction                                | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|  | Benadryl       |                  |                    | S               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Apr-2013  | 9217573        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013098889 |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Injury Associated With Device   | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Apr-2013  | 9174007        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013088596 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypoaesthesia  | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Apr-2013  | 9196407        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013095787 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Pain                               | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2013   | 9242436        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013120823 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain                                   | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Apr-2013   | 9229017        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013108185 |                      | 75 YR           | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pallor | Epipen         |                  |                    | S               |                          | 0.3 MI, As Needed    |                 | Pfizer     |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-May-2013   | 9175793        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013087297 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Incorrect Route Of Drug Administration; Tremor        | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-May-2013   | 9181276        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013088890 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain In Extremity                                     | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-May-2013   | 9210535        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013103258 |                      | 12 YR           | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                |                    |                    |                 |                          |                      |                 |            |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Haemorrhage; Injection Site Pain |                | Epipen             |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-May-2013   | 9176756        | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013088875 |                      | 19 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-May-2013   | 9213061        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013104339 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Jittery   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-May-2013   | 9219393        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013105360 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Energy Increased                                | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-May-2013   | 9271878        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013069222 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|---------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 10-May-2013  | 9284362                   | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013146571 |                      | 47 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Pain; Injection Site Pallor; Paraesthesia Oral; Vasoconstriction | Epipen<br>Diphenhydramine |                    |                    | S<br>C          |                          | 50 Mg, Single        |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-May-2013  | 9223283                   | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-2013111579 |                      | 8 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Drug Ineffective; Hypersensitivity; Respiratory Arrest   | Epipen                    |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-May-2013  | 9239130                   | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013117297 |                      | 54 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Fluctuation; Dysstasia; Hypersomnia; Weight Decreased   | Epipen                    |                    |                    | S               |                          | 0.3 Mg, As Needed    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-May-2013  | 9257529                   | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013126800 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen                    |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|-----------------------------|-----------------|------------|----------------|
| 21-May-2013                                  | 9257484        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013126814 |                             |                 | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain                          | Epipen         |                    |                    | S               |                          | Unk                         |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-May-2013                                  | 9266745        | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2013131415 |                             |                 | Unknown    | CAN            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury; Product Quality Issue | Epipen         |                    |                    | S               |                          | Unk                         |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-May-2013                                  | 9269542        | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-PFIZER INC-2013134512 |                             | 11 YR           | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Drug Ineffective             | Epipen         |                    |                    | S               |                          | Unk                         |                 | Pfizer     |                |
|  | Epipen         |                    |                    | S               |                          |                             |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-May-2013                                  | 9307810        | EXPEDITED (15-DAY) |                    | HO              | GB-PFIZER INC-2013157133 |                             |                 | Male       | GBR            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Rate Irregular; Tachycardia            | Epipen         |                    |                    | S               | Unknown                  | 1 Dosage Forms,1 In 1 Total |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-May-2013                                  | 9210932        | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2013091324 |                             | 53 YR           | Male       | GBR            |
| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>          | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |        |   |     |        |
|---|--------|---|-----|--------|
| Injection Site Bruising;<br>Injection Site<br>Haemorrhage; Injection<br>Site Pain; Product Quality<br>Issue | Epipen | S | Unk | Pfizer |
|---|--------|---|-----|--------|

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 29-May-2013              | 9314482        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2013158231 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Incomplete;  | Epipen         |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| Expired Product          | Epipen         |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| Administered             | Albuterol      |                  |                    | C               |                              | Unk                  |                 |            |                |

| <u>FDA Received Date</u> | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|--------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 04-Jun-2013              | 9316592            | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013137012 |                      | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event         | Epipen             |                  |                    | S               | Intramuscular                | 0.3 Mg, Prn          |                 | Pfizer     |                |
|                          | Cetirizine         |                  |                    | C               | Oral                         | 10 Mg, Qid           |                 |            |                |
|                          | Metformin          |                  |                    | C               | Oral                         | 500 Mg, 2x/Day       |                 |            |                |
|                          | Prilosec           |                  |                    | C               | Oral                         | 40 Mg, 1x/Day        |                 |            |                |
|                          | Warfarin           |                  |                    | C               | Oral                         | 5 Mg, 1x/Day         |                 |            |                |
|                          | Ativan             |                  |                    | C               | Oral                         | 1 Mg, Qhs            |                 |            |                |
|                          | Singulair          |                  |                    | C               | Oral                         | 10 Mg, Qhs           |                 |            |                |
|                          | Prozac             |                  |                    | C               | Oral                         | 40 Mg, 1x/Day        |                 |            |                |
|                          | Doxepin            |                  |                    | C               | Oral                         | 25 Mg, Qhs           |                 |            |                |
|                          | Oxycodone          |                  |                    | C               | Oral                         | 10 Mg, Q4h Prn       |                 |            |                |
|                          | Pro-Air            |                  |                    | C               |                              | 2 Puffs, Q4h         |                 |            |                |
|                          | Hydroxychloroquine |                  |                    | C               | Oral                         | 200 Mg, 2x/Day       |                 |            |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 05-Jun-2013   | 9290302        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013145043 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Haemorrhage; Pain In Extremity | Epipen         |                  |                    | S               | Intramuscular            | 1:1000, 0.3 MI, Prn  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2013   | 9291971        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2013146657 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |
|   | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |
|   | Benadryl       |                  |                    | S               |                          | Unk                  |                 |            |                |
|   | Benadryl       |                  |                    | S               |                          |                      |                 |            |                |
|   | Benadryl       |                  |                    | S               |                          |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2013   | 9295071        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013147879 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Pain   | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Jun-2013   | 9341294        | DIRECT           | Y                  | OT              |                          |                      | 60 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Haemorrhage; Injection Site Pain; Needle       | Epipen         |                  |                    | S               | Intramuscular            |                      |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 11-Jun-2013  | 9294760        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013147854 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Skin Burning Sensation  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Jun-2013  | 9296881        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013149504 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; Injection Site Injury   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Jun-2013  | 9302989        | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2013154206 |                      |                 | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Seizure  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Jun-2013  | 9315698        | EXPEDITED (15-DAY) |                    |                 | GB-PFIZER INC-2013164380 |                      | 40 YR           | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Heart Rate Increased; Hyperhidrosis; Injection Site Bruising; Injection Site Paraesthesia; Injection Site Swelling; Respiratory Rate Increased | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------------------|--------------------|--------------------|-----------------|--------------------------|--------------------------------------|-----------------|------------|----------------|
| 27-Jun-2013   | 9330234                          | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013168181 |                                      | 9 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Disorder  | Epipen                           |                    |                    | S               | Subcutaneous             | Unk                                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Jun-2013   | 9359245                          | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013180747 |                                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen                           |                    |                    | S               | Intramuscular            | 0.3 Mg, As Needed                    |                 | Pfizer     |                |
|   | Albuterol Solution For Nebulizer |                    |                    | C               | Oral                     | Unk                                  |                 |            |                |
|   | Proventil Mdi                    |                    |                    | C               | Oral                     | Unk, As Needed                       |                 |            |                |
|   | Advair                           |                    |                    | C               | Oral                     | Unk                                  |                 |            |                |
|   | Spironolactone                   |                    |                    | C               | Oral                     | 25 Mg, 1x/Day                        |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jul-2013   | 9336618                          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013170941 |                                      | 40 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Bruising; Injection Site Pallor; Limb Discomfort | Epipen Jr                        |                    |                    | S               |                          | 1:2000, 0.3 MI, 1 Time (1 Injection) |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Jul-2013   | 9349268                          | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2013175017 |                                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen                           |                    |                    | S               |                          | Unk                                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 02-Jul-2013  | 9349529        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013175022 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fatigue  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Jul-2013  | 9395154        | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2013199164 |                      |                 | Male       | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Haemorrhage  | Epipen         |                    |                    | S               | Intramuscular            |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2013  | 9343164        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013172697 |                      | 23 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia; Pallor; Paraesthesia    | Epipen         |                    |                    | S               |                          | 1:1000, 0.3 MI       |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2013  | 9351273        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013177838 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; Gait Disturbance; Pain; Peripheral Swelling | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2013  | 9365043        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013184839 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                  |                                 |   |      |   |        |
|------------------|---------------------------------|---|------|---|--------|
| Drug Ineffective | Epipen                          | S |      | 0.3 MI, As Needed Twice Daily             | Pfizer |
|                  | Armour Thyroid                  | C | Oral | 30 Mg, 1x/Day                             |        |
|                  | Potassium Chloride              | C | Oral | 20 Meq, 2x/Day                            |        |
|                  | Hydrochlorothiazide/Triamterene | C | Oral | 37.5/25 Mg, Daily                         |        |
|                  | Clonazepam                      | C | Oral | 0.5 Mg, (1/2 To 1 Tablet Daily) As Needed |        |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 15-Jul-2013  | 9353880        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2013178189 |                      | 57 YR           | Female     | USA            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Arthralgia;<br>Musculoskeletal Discomfort; Seizure | Epipen         |                  |                    | S               | Subcutaneous             | 0.3 Mg, As Needed    |                 | Pfizer     |                |
|  | Benadryl       |                  |                    | S               |                          | Unk                  |                 |            |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 15-Jul-2013              | 9355732        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013179544 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain                     | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 15-Jul-2013   | 9363075        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013183514 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 16-Jul-2013              | 9356266       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013179550 |                      | 87 YR      | Male       | USA            |

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| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------------------------|--------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|------------|----------------|
| Drug Ineffective; Expired Product Administered; Product Quality Issue        | Epipen                           |                    |                    | S               | Intramuscular            | 0.30 Mg, As Needed     |                 | Pfizer     |                |
|  | Hydrochlorothiazide              |                    |                    | C               | Oral                     | 25 Mg, 1x/Day          |                 |            |                |
|  | Sertraline                       |                    |                    | C               | Oral                     | 100 Mg, 1x/Day         |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jul-2013  | 9357973                          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013179515 |                        | 73 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Coldness; Injection Site Pain | Epipen                           |                    |                    | S               |                          | 1:1000, 0.3 MI, 1 Time |                 | Pfizer     |                |
|  | Actonel                          |                    |                    | C               | Oral                     | 150 Mg, Monthly        |                 |            |                |
|  | Metformin                        |                    |                    | C               | Oral                     | 500 Mg, 2tabs Bid      |                 |            |                |
|  | Lisinopril W/Hydrochlorothiazide |                    |                    | C               | Oral                     | 20/12.5 Mg             |                 |            |                |
|  | Simvastatin                      |                    |                    | C               | Oral                     | 40 Mg Daily            |                 |            |                |
|  | Finasteride                      |                    |                    | C               | Oral                     | 5 Mg Daily             |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jul-2013  | 9366149                          | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013185047 |                        |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Loss Of Consciousness  | Epipen                           |                    |                    | S               |                          | Unk                    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jul-2013  | 9369530                          | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013188786 |                        |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen                           |                    |                    | S               |                          | Unk                    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jul-2013  | 9375804                          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-           |                        | 35 YR           | Male       | USA            |

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| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|------------------|--------------------|-----------------|--------------------------|-----------------------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Asthenia; Migraine; Nausea; Tremor | Epipen         |                  |                    | S               | Intramuscular            | 0.3 Mg, As Needed                 |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Jul-2013  | 9321014        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013164252 |                                   | 38 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion  | Epipen         |                  |                    | S               |                          | Unk                               |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Jul-2013  | 9397049        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013202402 |                                   |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain  | Epipen         |                  |                    | S               |                          | Unk                               |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Jul-2013  | 9390944        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2013198195 |                                   | 47 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen         |                  |                    | S               | Intramuscular            | 0.3 Mg, As Needed, 1:1000, 0.3 MI |                 | Pfizer     |                |
|  | Epipen         |                  |                    | S               |                          | 0.3 Mg, As Needed                 |                 | Pfizer     |                |
|  | Benadryl       |                  |                    | C               | Oral                     | 50 Mg, 2 Tablets Every 4 Hrs      |                 |            |                |
|  | Vitamin B1     |                  |                    | C               | Oral                     | 100 Mg, 1x/Day                    |                 |            |                |
|  | Omeprazole     |                  |                    | C               | Oral                     | 20 Mg, 1x/Day                     |                 |            |                |



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|                      |   |         |                  |
|----------------------|---|---------|------------------|
| Lisinopril           | C | Oral    | 10 Mg, 1x/Day    |
| Vitamins             | C | Oral    | Unk, Qd          |
| Acetylsalicylic Acid | C | Oral    | 81 Mg, 1x/Day    |
| Lactulose            | C | Oral    | 10 Gm/15 ML, Bid |
| Colestyramine        | C | Oral    | Unk              |
| Ibuprofen            | C | Unknown | Unk, Prn         |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 18-Jul-2013              | 9394630       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013201470 |                      |            | Female     | USA            |

| <u>Preferred Term</u>                   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product By Child | Epipen         |              |            | S           | Unknown      | 0.3 Mg, Unk        |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 22-Jul-2013              | 9418947       | DIRECT           | Y                  |                 |                      |                      | 11 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Incorrect Drug Administration Duration; Wrong Technique In Product Usage Process | Epipen         |              |            | S           | Intramuscular |                    |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 25-Jul-2013              | 9422575       | DIRECT           | Y                  |                 |                      |                      | 49 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Circumstance Or Information Capable Of Leading To Medication Error; Drug Administration Error | Epipen         |              |            | S           | Cutaneous    |                    |                 | Dey        |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|------------|----------------|
| 29-Jul-2013  | 9425268        | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2013219614 |                        | 3 YR            | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Application Site Bruise;<br>Device Malfunction;<br>Emotional Distress              | Epipen Jr      |                    |                    | S               |                          | Unk                    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jul-2013  | 9426446        | DIRECT             |                    | LT              |                          |                        | 65 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Atrial Fibrillation; Blood<br>Pressure Increased                                   | Epipen         |                    |                    | S               |                          |                        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jul-2013  | 9392932        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013198217 |                        | 36 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Pain In Extremity;<br>Pain In Extremity; Tremor | Epipen Jr      |                    |                    | S               |                          | 1:2000, 0.3 MI, Single |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jul-2013  | 9405572        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013206079 |                        |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Pain   | Epipen         |                    |                    | S               |                          | Unk                    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jul-2013  | 9407663        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013206332 |                        | 16 YR           | Female     | USA            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|------------------|--------------------|-----------------|--------------------------|------------------------------|-----------------|------------|----------------|
| Drug Effect Delayed  | Epipen         |                  |                    | S               | Intramuscular            | 0.6 Mg, As Needed            |                 | Pfizer     |                |
|  | Buspar         |                  |                    | C               | Oral                     | Unk                          |                 |            |                |
|  | Zoloft         |                  |                    | C               | Oral                     | Unk                          |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jul-2013  | 9418733        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013213109 |                              | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Expired Product Administered; Nervousness | Epipen         |                  |                    | S               |                          | Unk                          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Aug-2013  | 9415444        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013210577 |                              |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Psychomotor Hyperactivity                          | Epipen         |                  |                    | S               |                          | Unk                          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Aug-2013  | 9423404        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2013215727 |                              | 30 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Quality Issue  | Epipen         |                  |                    | S               | Intramuscular            | 0.3 Mg, As Needed, Two Doses |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2013  | 9440648        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013222423 |                              |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                |                    |                    |                 |                              |                      |                 |            |                |
|---|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| Injection Site<br>Haemorrhage; Injury<br>Associated With Device;<br>Peripheral Swelling         | Epipen         |                    | S                  |                 |                              | Unk                  |                 |            | Pfizer         |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2013   | 9450825        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013208849 |                      | 62 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Incomplete  | Epipen         |                    |                    | S               | Intramuscular                | 0.3 Mg, As Needed    |                 |            | Pfizer         |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Aug-2013   | 9439655        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-<br>2013222723 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                    |                    | S               |                              | Unk                  |                 |            | Pfizer         |
|   | Epipen         |                    |                    | S               |                              |                      |                 |            | Pfizer         |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Aug-2013   | 9439703        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2013222504 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injection Site<br>Pain                                       | Epipen Jr      |                    |                    | S               |                              | Unk                  |                 |            | Pfizer         |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2013   | 9397550        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2013201484 |                      | 39 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Expired Product<br>Administered;<br>Hyperhidrosis; Injection | Epipen         |                    |                    | S               |                              | Unk                  |                 |            | Pfizer         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Site Bruising; Injection Site  
Hypoaesthesia; Injection  
Site Pain; Vomiting

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 16-Aug-2013              | 9461244        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013235457 |                      | 83 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Flushing; Pain           | Epipen         |                  |                    | S               | Intramuscular            | 0.30 Mg, Unk         |                 | Pfizer     |                |
|                          | Fish Oil       |                  |                    | C               |                          | Unk                  |                 |            |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 20-Aug-2013                                       | 9466984        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013237747 |                      | 21 YR           | Female     | USA            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; Injection Site Pain | Epipen         |                  |                    | S               | Intramuscular            | 0.3 Mg, As Needed    |                 | Pfizer     |                |
|   | Albuterol      |                  |                    | C               | Respiratory (inhalation) | Prn, Unk             |                 |            |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 21-Aug-2013              | 9447468        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013226418 |                      | 30 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Tremor                   | Epipen         |                  |                    | S               | Intramuscular            | 0.3 Mg, As Needed    |                 | Pfizer     |                |
|                          | Epipen         |                  |                    | S               |                          |                      |                 | Pfizer     |                |

| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 21-Aug-2013                            | 9472230        | DIRECT           |                    |                 |                      |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Circumstance Or Information Capable Of | Epipen         |                  |                    | S               |                      |                      |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leading To Medication  
Error; Medication Error

| <u>FDA Received Date</u>  | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|-------------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 22-Aug-2013   | 9422619           | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013215786 |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired<br>Product Administered;<br>Insomnia; Restless Legs<br>Syndrome; Somnolence | Epipen            |                  |                    | S               | Intramuscular                | 0.3 Mg, As Needed    |                 | Pfizer     |                |
|   | Epipen            |                  |                    | S               |                              |                      |                 | Pfizer     |                |
|   | Benadryl          |                  |                    | S               | Unknown                      | Unk                  |                 |            |                |
|   | Tramadol          |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
|   | Valium            |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
|   | Pravastatin       |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
|   | Glyburide         |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
|   | Strattera         |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
|   | Vesicare          |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
|   | Pulmicort         |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
|   | Zolpidem Tartrate |                  |                    | C               | Unknown                      | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Aug-2013   | 9443523           | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013223700 |                      | 58 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain;<br>Product Quality Issue   | Epipen            |                  |                    | S               |                              | 0.3 Mg Prn           |                 | Pfizer     |                |
|   | Benadryl          |                  |                    | C               |                              | Unk, Prn             |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Aug-2013   | 9449631           | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2013227871 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen            |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|--------------------------|-----------------|------------|----------------|
| 22-Aug-2013  | 9471046        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013239820 |                          | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen         |                    |                    | S               |                          | 0.3 Mg, Single           |                 | Pfizer     |                |
|  | Benadryl       |                    |                    | C               | Oral                     | Unk                      |                 |            |                |
|  | Albuterol      |                    |                    | C               | Oral                     | Prn                      |                 |            |                |
|  | Effexor-Xr     |                    |                    | C               | Oral                     | 300 Mg Am, 75 Mg At Noon |                 |            |                |
|  | Topamax        |                    |                    | C               | Oral                     | 50 Mg Am, 150 Mg Hs      |                 |            |                |
|  | Lantus         |                    |                    | C               | Subcutaneous             | 30 Units Am, 30 Units Pm |                 |            |                |
|  | Nexium         |                    |                    | C               | Oral                     | Qam                      |                 |            |                |
|  | Ativan         |                    |                    | C               | Oral                     | 4mg, Unk                 |                 |            |                |
|  | Singulair      |                    |                    | C               | Oral                     | Hs                       |                 |            |                |
|  | Trazodone      |                    |                    | C               | Oral                     | 100 Mg, Hs               |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Aug-2013  | 9471061        | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2013243722 |                          | 2 YR            | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Pain; Procedural Complication; Wound               | Epipen         |                    |                    | S               | Intramuscular            | 0.15 Mg, As Needed       |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Aug-2013  | 8874815        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2012259314 |                          | 73 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Arthralgia; Back Pain; Blood Pressure Increased; Headache; Product | Epipen         |                    |                    | S               |                          | Unk                      |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Quality Issue; Tendonitis;  
Trigger Finger

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 23-Aug-2013              | 9474789        | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2013245236 |                      | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen         |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>                  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 26-Aug-2013                               | 9461272        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013234130 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Tremor | Epipen         |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 26-Aug-2013                                       | 9475804        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013242619 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired<br>Product Administered | Epipen         |                  |                    | S               |                              | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 27-Aug-2013   | 9458049        | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013231563 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Expired Product<br>Administered; Injection<br>Site Hypoaesthesia | Epipen         |                  |                    | S               | Unknown                      | 0.3 Mg, Unk          |                 | Pfizer     |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 27-Aug-2013  | 9479380        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013244993 |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Injury; Pain In Extremity; Product Quality Issue                                    | Epipen         |                    |                    | S               |                          | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Aug-2013  | 9460126        | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013232536 |                      | 32 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Haemorrhage; Injection Site Hypoaesthesia; Peripheral Coldness; Skin Discolouration | Epipen         |                    |                    | S               |                          | 0.3 MI, As Needed    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Aug-2013  | 9486242        | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2013247004 |                      | 19 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Swollen Tongue; Urticaria  | Epipen         |                    |                    | S               | Intramuscular            | 0.3 Mg, As Needed    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Aug-2013  | 9490901        | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013246847 |                      | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                 |                    |                    |                   |                                       |                                 |                 |            |                |
|---------------------------------------|-----------------|--------------------|--------------------|-------------------|---------------------------------------|---------------------------------|-----------------|------------|----------------|
| Drug Ineffective                      | Epipen          | S                  | Intramuscular      | 0.3 Mg, As Needed |                                       |                                 |                 | Pfizer     |                |
|                                       | Zolpidem        | C                  | Oral               | 10 Mg, As Needed  |                                       |                                 |                 |            |                |
| <u>FDA Received Date</u>              | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>                  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Aug-2013                           | 9491936         | NON-EXPEDITED      |                    | HO                | US-PFIZER INC-2013246858              |                                 | 63 YR           | Male       | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>       | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                      | Epipen          |                    |                    | S                 | Unknown                               | 0.3 Mg, As Needed               |                 | Pfizer     |                |
|                                       | Metformin       |                    |                    | C                 | Oral                                  | 500 Mg, Unk                     |                 |            |                |
|                                       | Lisinopril      |                    |                    | C                 | Oral                                  | Unk                             |                 |            |                |
|                                       | Gabapentin      |                    |                    | C                 | Oral                                  | Hs                              |                 |            |                |
|                                       | Trazodone       |                    |                    | C                 | Oral                                  | Hs                              |                 |            |                |
|                                       | Benadryl        |                    |                    | C                 |                                       | 25 Mgx1 Approx <1 Min           |                 |            |                |
| <u>FDA Received Date</u>              | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>                  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Sep-2013                           | 9494523         | EXPEDITED (15-DAY) |                    | DE, OT            | US-PFIZER INC-2013251022              |                                 | 8 YR            | Male       | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>       | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Cyanosis; Hypotension | Epipen          |                    |                    | S                 | Intravenous (not otherwise specified) | Unk                             |                 | Pfizer     |                |
|                                       | Diphenhydramine |                    |                    | C                 |                                       | Unk                             |                 |            |                |
|                                       | Albuterol       |                    |                    | C                 |                                       |                                 |                 |            |                |
|                                       | Flovent         |                    |                    | C                 |                                       | 110 Mcg 2 Puffs Two Times A Day |                 |            |                |
|                                       | Zyrtec          |                    |                    | C                 |                                       | 5 Mg, As Needed                 |                 |            |                |
|                                       | Albuterol       |                    |                    | C                 |                                       | 2 Puffs As Needed               |                 |            |                |
| <u>FDA Received Date</u>              | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>                  | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Sep-2013                           | 9446412         | EXPEDITED (15-DAY) |                    | DE                | US-PFIZER INC-2013221268              |                                 | 13 YR           | Female     | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>       | <u>Route</u>                          | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                     |                  |                    |                 |                              |  |                 |            |                |
|--|---------------------|------------------|--------------------|-----------------|------------------------------|--|-----------------|------------|----------------|
| Drug Ineffective;<br>Hypersensitivity;<br>Laryngeal Oedema                                 |                     | Epipen           | S                  |                 | 3 Df (Epipens), Unk          |  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Sep-2013  | 9450455             | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2013227842 |  | 33 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Energy<br>Increased; Therapeutic<br>Response Unexpected | Epipen              |                  |                    | S               |                              | 0.3 Mg, As Needed                                |                 | Pfizer     |                |
|  | Albuterol           |                  |                    | C               | Respiratory<br>(inhalation)  | Unk  |                 |            |                |
|  | Protonix            |                  |                    | C               | Oral                         | Unk  |                 |            |                |
|  | Hydrochlorothiazide |                  |                    | C               | Oral                         | Unk  |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2013  | 9503159             | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2013253388 |  |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen              |                  |                    | S               |                              | 0.3 Mg, Prn                                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>                             | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2013  | 9503186             | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-<br>2013252080 |  | 73 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>                               | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product<br>Quality Issue   | Epipen              |                  |                    | S               | Intramuscular                | 0.3 Mg, 1x/Day                                   |                 | Pfizer     |                |
|  | Verapamil           |                  |                    | C               | Oral                         | 240 Mg, 1x/Day                                   |                 |            |                |
|  | Simvastatin         |                  |                    | C               | Oral                         | 20 Mg, 1x/Day                                    |                 |            |                |
|  | Losartan            |                  |                    | C               | Oral                         | 50 Mg, 1x/Day                                    |                 |            |                |
|  | Lyrice              |                  |                    | C               | Oral                         | 150 Mg, 2x/Day                                   |                 |            |                |
|  | Advair              |                  |                    | C               | Oral                         | 500/50 Mg (1000/100mg)<br>In Morning And Evening |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|            |   |      |     |
|------------|---|------|-----|
| Paroxetine | C | Oral | Unk |
| Albuterol  | C | Oral | Prn |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 06-Sep-2013              | 9503332       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2013253376 |                      | 38 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Pain | Epipen         |              |            | S           | Intramuscular | 0.3 Mg             |                 | Pfizer     |
|  | Propanolol     |              |            | C           | Oral          | 20 Mg, 1x/Day      |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 12-Sep-2013              | 9520461       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1019857 |                      | 28 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pallor | Epipen Jr      |              |            | S           | Intramuscular |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 19-Sep-2013              | 9537061       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013270002 |                      |            | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Blood Pressure Abnormal; Erythema; Headache; Peripheral Swelling; Swelling Face | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 23-Sep-2013              | 9546566       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1021104 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |                    |                    |                 |                               |                      |                 |            |                |
|--|--------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Drug Effect Decreased;<br>Dyspnoea; Expired<br>Product Administered  |                          | Epipen             |                    | S               |                               |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Sep-2013  | 9557975                  | EXPEDITED (15-DAY) |                    | HO, OT          | GB-MYLANLABS-<br>2013S1021187 |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen                   |                    |                    | S               |                               |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Sep-2013  | 9565302                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2013S1021668 |                      | 54 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose<br>Omission  | Epipen 2-Pak<br>Benadryl |                    |                    | S<br>C          | Intramuscular                 |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Sep-2013  | 9565593                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2013S1021667 |                      | 9 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection<br>Site Bruising   | Epipen 2-Pak             |                    |                    | S               | Intramuscular                 |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Oct-2013  | 9601240                  | EXPEDITED (15-DAY) |                    | LT, OT          | AU-MYLANLABS-<br>2013S1021394 |                      | 64 YR           | Female     | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Deployment Issue;<br>Drug Ineffective; Injection<br>Site Bruising; Injection Site<br>Discolouration; Pain In<br>Extremity | Epipen                   |                    |                    | S               | Intramuscular                 |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 14-Oct-2013  | 9618969        | EXPEDITED (15-DAY) |                    | OT              | FI-MYLANLABS-2013S1022899 |                      | 5 YR            | Female     | FIN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen         |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Oct-2013  | 9628867        | EXPEDITED (15-DAY) |                    | HO              | BE-MYLANLABS-2013S1023101 |                      | 54 YR           | Female     | BEL            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Paraesthesia; Wrong Technique In Product Usage Process | Epipen         |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
|  | Adrenaline     |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Oct-2013  | 9639113        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1023249 |                      | 41 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission                                       | Epipen         |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Oct-2013  | 9640701        | DIRECT             |                    | OT              |                           |                      | 67 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Amnesia; Anaphylactic Shock; Angina Pectoris; Muscle Spasms              | Epi Pen        |                    |                    | S               |                           | 1 Dose               |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Oct-2013  | 9548221        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1021049 |                      | 33 YR           | Female     | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure   | Epipen 2-Pak            |                           |                             | S                        | Intramuscular                 |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 31-Oct-2013  | 9659661                 | EXPEDITED (15-DAY)        |                             | DE                       | US-MYLANLABS-2013S1024231     |                               | 58 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Effect Decreased  | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Nov-2013  | 9667981                 | NON-EXPEDITED             |                             | DE                       | US-PFIZER INC-2013312454      |                               | 58 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Effect Decreased  | Epipen                  |                           |                             | S                        |                               | 0.3 Mg, Unk                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Nov-2013  | 9671112                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2013313896      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Hot Flush; Hypersensitivity  | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, As Needed             |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Nov-2013  | 9677455                 | DIRECT                    |                             | DS, HO, LT, OT           |                               |                               | 1 YR                     | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaphylactic Shock; Disturbance In Attention; Skin Discolouration; Unresponsive To Stimuli | Epi Pen                 |                           |                             | S                        |                               | 2 Shots, Into The Muscle      |                          | Mylan               |                         |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 13-Nov-2013   | 9686664              | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1025239 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Seizure   | Epipen Jr 2-Pak      |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Nov-2013   | 9563922              | EXPEDITED (15-DAY) |                    | DE              | CA-JNJFOC-20130913853     |                      | 13 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective;<br>Dyspnoea; Pharyngeal<br>Oedema; Vomiting | Benadryl Unspecified |                    | Y                  | S               | Oral                      |                      |                 |            |                |
|   | Epipen               |                    |                    | S               | Unknown                   |                      |                 |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Nov-2013   | 9691318              | EXPEDITED (15-DAY) |                    | LT              | CA-MYLANLABS-2013S1025342 |                      | 58 YR           | Male       | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen<br>Crestor    |                    |                    | S<br>C          |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Nov-2013   | 9703915              | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2013331315  |                      | 38 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity   | Aldactone            |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|   | Prevacid             |                    |                    | S               |                           | Unk                  |                 |            |                |
|   | Albuterol            |                    |                    | S               |                           | Unk                  |                 |            |                |
|   | Synthroid            |                    |                    | S               |                           | Unk                  |                 |            |                |



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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 27-Nov-2013  | 9716093        | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2013S1026464 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; Hypersensitivity; Reaction To Excipient  | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Dec-2013  | 9731980        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1027038 |                      | 14 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Device Used  | Epipen         |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
|  | Epipen         |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Dec-2013  | 9745851        | DIRECT             |                    | LT              |                           |                      | 62 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea; Fall; Flushing; Hyperhidrosis; Hypersensitivity; Loss Of Consciousness; Respiratory Arrest; Vomiting | Amoxicillin    |                    |                    | S               | Oral                      |                      |                 | Aurobindo  |                |
|  | Epipen         |                    |                    | S               | Intramuscular             |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2013  | 9771154        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2013S1027721 |                      | 67 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Amnesia; Blood Pressure Systolic Increased; Chest  | Epipen         |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |

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|  |   |   |      |
|--|---|---|------|
| Discomfort; Chest Pain;<br>Drug Ineffective; Seizure | Clonidine Hydrochloride Tablets,<br>Usp | S | Oral |
|  | Niacin                                  | C |      |
|  | Montelukast                             | C |      |
|  | Fluticasone                             | C |      |
|  | Diazepam                                | C |      |
|  | Phenobarbital                           | C |      |
|  | Hydrochlorothiazide                     | C |      |
|  | Levothyroxine                           | C |      |
|  | Calcium                                 | C |      |
|  | Vitamin D                               | C |      |
|  | Multivitamin                            | C |      |
|  | Miralax /00754501/                      | C |      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 18-Dec-2013              | 9771311       | EXPEDITED (15-DAY) |                    | HO              | GB-MYLANLABS-<br>2013S1027493 |                      |            | Male       | GBR            |

| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To<br>Product; Loss Of<br>Consciousness | Epipen         |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 23-Dec-2013              | 9779476       | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-<br>2013S1028326 |                      | 45 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Anaphylactic Reaction;<br>Device Failure; Drug<br>Ineffective | Epipen         |              |            | S           | Intramuscular |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 31-Dec-2013              | 9790574       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2013S1028931 |                      | 31 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure        | Epipen 2-Pak   |              |            | S           | Intramuscular |                    |                 | Mylan      |

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| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 02-Jan-2014   | 9793398                   | EXPEDITED (15-DAY) |                    | OT              | US-ABBVIE-13P-163-1183846-00 |                      | 56 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device; Peripheral Vascular Disorder   | Humira                    |                    |                    | S               | Subcutaneous                 |                      |                 |            |                |
|   | Humira                    |                    |                    | S               |                              |                      |                 |            |                |
|   | Epipen                    |                    |                    | S               |                              |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Jan-2014   | 9691336                   | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2013S1025467    |                      | 66 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen 2-Pak              |                    |                    | S               | Intramuscular                |                      |                 |            | Mylan          |
|   | Lisinopril                |                    |                    | C               | Oral                         | Took For Years       |                 |            |                |
|   | Mobic                     |                    |                    | C               |                              |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Jan-2014   | 9812793                   | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2014S1000501    |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen                    |                    |                    | S               |                              |                      |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jan-2014   | 9772214                   | EXPEDITED (15-DAY) |                    | DS, HO, LT      | US-MYLANLABS-2013S1027982    |                      | 37 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Clostridial Infection; Injection Site Injury; Myositis; Necrotising Fasciitis; Pain In Extremity; Sepsis; Unevaluable Event | Epipen 2-Pak              |                    |                    | S               | Intramuscular                |                      |                 |            | Mylan          |
|   | Blood Pressure Medication |                    |                    | C               |                              |                      |                 |            |                |
|   | Cholesterol Medication    |                    |                    | C               |                              |                      |                 |            |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Jan-2014   | 9820459        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1000522 |                      | 6 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Injury Associated With Device  | Epipen Jr      |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jan-2014   | 9820490        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1000389 |                      | 2 YR            | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Foreign Body; Injection Site Injury; Needle Issue   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jan-2014   | 9821014        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1000517 |                      | 57 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Circumstance Or Information Capable Of Leading To Medication Error; Device Failure; Drug Effect Decreased; Hypersensitivity | Epipen 2-Pak   |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jan-2014   | 9853381        | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2014S1001704 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Product Misuse  | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Jan-2014   | 9858520        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1001780 |                      |                 | Female     | USA            |

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| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Injection Site Bruising; Injury Associated With Device; Needle Issue; Wrong Technique In Product Usage Process | Epipen         |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Feb-2014  | 9868100        | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2014S1002181 |                      | 77 YR           | Male       | SWE            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Feb-2014  | 9889633        | EXPEDITED (15-DAY) |                    | DE              | CA-MYLANLABS-2014S1002167 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Complication Of Device Insertion   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911791        | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2012S1021594 |                      | 73 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Arthralgia; Back Pain; Blood Pressure Increased; Headache; Product Quality Issue; Tendonitis; Trigger Finger   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911792        | NON-EXPEDITED      |                    | OT              | US-MYLANLABS-2013S1001538 |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|   |                |                  |                    |                 |                           |                      |                    |                 |                |
|---|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| Drug Ineffective                                    | Epipen         |                  |                    | S               |                           |                      |                    |                 | Mylan          |
|   | Epipen         |                  |                    | S               |                           |                      |                    |                 | Mylan          |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9911793        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-2013S1001636 |                      |                    | Male            | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective                                    | Epipen         |                  |                    |                 | S                         |                      |                    |                 | Mylan          |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9911794        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001710 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product                      | Epipen         |                  |                    |                 | S                         |                      |                    |                 | Mylan          |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9911795        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001711 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Injection Site Pain | Epipen         |                  |                    |                 | S                         |                      |                    |                 | Mylan          |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9911796        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001717 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Insomnia  | Epipen         |                  |                    |                 | S                         |                      |                    |                 | Mylan          |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9911797        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001719 |                      | 33 YR              | Female          | USA            |

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| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|-----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Blood Pressure Increased; Heart Rate Increased; Injection Site Injury  | Epipen          |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911798         | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001720 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Wrong Technique In Product Usage Process | Epipen          |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911799         | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001874 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen          |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911800         | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001875 |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Product Quality Issue                             | Epipen<br>Aleve |                  |                    | S<br>C          |                           |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014  | 9911801          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001876 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Flushing; Palpitations; Product Quality Issue                         | Epipen<br>Motrin |                  |                    | S<br>C          | Subcutaneous              |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911802          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001877 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Feeling Jittery  | Epipen           |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911803          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001879 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Hypoaesthesia; Palpitations; Peripheral Coldness | Epipen           |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911804          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001935 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device  | Epipen           |                  |                    | S               |                           |                      |                 | Mylan      |                |



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| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 19-Feb-2014  | 9911805                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1002212     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product   | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014  | 9911806                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1002226     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product   | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014  | 9911807                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1002232     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Expired Product Administered; Head Discomfort; Injection Site Bruising; Nervousness; Pain In Extremity; Paraesthesia; Peripheral Swelling; Skin Discolouration; Somnolence | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014  | 9911808                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1002236     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To   | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product

| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|--|------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|----------------|----------------|
| 19-Feb-2014  | 9911811          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1002361 |                      |                 | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product   | Epipen<br>Epipen |                  |                    | S<br>S          |                           |                      |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911812          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1002417 |                      |                 | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Product Label Issue; Product Storage Error   | Epipen           |                  |                    | S               |                           |                      |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911813          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1002455 |                      | 4 YR            | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Injection Site Haemorrhage; Injection Site Injury; Injection Site Pain | Epipen Jr        |                  |                    | S               |                           |                      |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911814          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1001915 |                      |                 | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Heart Rate Increased   | Epipen           |                  |                    | S               |                           |                      |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911815          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-             |                      | 50 YR           | Female         | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2013S1002702

| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
|--|------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|----------------|----------------|
| Accidental Exposure To Product; Contusion; Product Quality Issue | Epipen Jr        |                  |                    | S               |                           |                      |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911817          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1003452 |                      | 5 YR            | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Contusion; Peripheral Swelling   | Epipen Jr        |                  |                    | S               |                           |                      |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911818          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1006498 |                      |                 | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Incorrect Route Of Drug Administration; Tremor                   | Epipen           |                  |                    | S               |                           | Unk                  |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911819          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1003520 |                      | 4 YR            | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Drug Administration Error  | Epipen<br>Epipen |                  |                    | S<br>S          |                           |                      |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>   | <u>Case #</u>    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9911821          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1004118 |                      |                 | Male           | USA            |

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| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|-----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product   | Epipen          |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911822         | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1004597 |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity  | Epipen<br>Vioxx |                  |                    | S<br>S          |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911823         | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1004709 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Quality Issue; Wrong Technique In Product Usage Process                    | Epipen          |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911825         | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1005481 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen          |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911826         | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1005762 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Circumstance Or Information Capable Of Leading To Medication Error; Product Colour | Epipen          |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Issue

| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014                        | 9911827        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1005769 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Injection Site Bruising | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                        | 9911828        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1005782 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Euphoric Mood                      | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
|                                    | Benadryl       |                  |                    | S               |                           | 2 Shots              |                 | Mylan      |                |
|                                    | Zantac         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                        | 9911829        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1006117 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product     | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                        | 9911831        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1006497 |                      | 9 YR            | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product     | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 19-Feb-2014                              | 9911832                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1006500     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypoaesthesia                            | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                              | 9911833                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1006682     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pain In Extremity; Product Quality Issue | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                              | 9911834                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1007124     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product           | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                              | 9911835                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1007125     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Pain                   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                              | 9911839                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1007510     |                               | 12 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To                   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Product; Injection Site  
Haemorrhage; Injection  
Site Pain

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911840        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1007741 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Heart Rate<br>Increased; Palpitations        | Epipen         |                  |                    | S               |                               | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911841        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1007742 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Jittery; Product<br>Quality Issue                                       | Epipen         |                  |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911843        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1007743 |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Injury<br>Associated With Device;<br>Product Quality Issue | Epipen         |                  |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911844        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1007832 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Energy Increased                             | Epipen         |                  |                    | S               |                               | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911845        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1007837 |                      | 75 YR           | Female     | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pallor   | Epipen         |                  |                    | S               |                           | 0.3ml, As Needed     |                 | Mylan      |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911847        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1008213 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Product Label Confusion | Epipen Jr      |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911850        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1008801 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain                                     | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911851        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-2013S1009262 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911853        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1009263 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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|  |                |                  |                    |                 |                               |                      |                 |            |                |
|--|----------------|------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Injection Site Pain;<br>Product Quality Issue                                |                | Epipen           |                    | S               |                               |                      | Unk             |            | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911859        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1010069 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product  | Epipen         |                  |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911860        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1010262 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Product Quality<br>Issue                  | Epipen         |                  |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911861        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1010400 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Product Quality<br>Issue                  | Epipen         |                  |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911862        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1010604 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Product Quality<br>Issue; Self-Medication | Epipen         |                  |                    | S               |                               | Unk                  |                 | Mylan      |                |
|  | Zolof          |                  |                    | C               |                               | Unk                  |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 19-Feb-2014  | 9911863        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1010686 |   | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Haemorrhage; Pain In Extremity        | Epipen         |                  |                    | S               | Intramuscular             | 1:1000, 0.3 MI, Prn                               |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911864        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1010687 |   | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen         |                  |                    | S               | Subcutaneous              | (Dose Unit: 1:2000, 0.3 MI), (Daily Dose: 0.5 Mg) |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911865        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1010999 |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Skin Burning Sensation  | Epipen         |                  |                    | S               |                           | Unk   |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911866        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1011000 |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                                | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Injection Site Bruising; Injection Site Pain; Pain; Product Quality Issue | Epipen         |                  |                    | S               |                           | Unk   |                 | Mylan      |                |

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| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|---------------------------|--------------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911867        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1011002 |                          | 9 YR            | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child               | Epipen         |                  |                    | S               | Intramuscular             | 0.3 MI, 1x/Day, (1:1000) |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911868        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1011508 |                          |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                        | Epipen         |                  |                    | S               |                           | Unk                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911869        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1011858 |                          |                 | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Product Quality Issue | Epipen         |                  |                    | S               |                           | Unk                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911870        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1012035 |                          | 38 YR           | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion   | Epipen         |                  |                    | S               |                           | Unk                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911871        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1012742 |                          |                 | Male       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
|   |                |                  |                    |                 |                           |                          |                 |            |                |

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|   |                     |                  |                    |                 |                           |                                      |                 |            |                |
|---|---------------------|------------------|--------------------|-----------------|---------------------------|--------------------------------------|-----------------|------------|----------------|
| Accidental Exposure To Product  | Epipen              |                  | S                  |                 |                           | Unk                                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911872             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1012773 |                                      | 40 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Bruising; Injection Site Pallor; Limb Discomfort | Epipen Jr.          |                  |                    | S               |                           | 1:2000, 0.3 MI, 1 Time (1 Injection) |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911873             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1013287 |                                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Fatigue   | Epipen              |                  |                    | S               |                           | Unk                                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911874             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1013699 |                                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain  | Epipen              |                  |                    | S               |                           | Unk                                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911875             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1013700 |                                      | 87 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered; Product Quality Issue                           | Epipen              |                  |                    | S               | Intramuscular             | 0.30 Mg, As Needed                   |                 | Mylan      |                |
|   | Hydrochlorothiazide |                  |                    | C               | Oral                      | 25 Mg, 1x/Day                        |                 |            |                |
|   | Sertraline          |                  |                    | C               | Oral                      | 100 Mg, 1x/Day                       |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------------------|------------------|--------------------|-----------------|---------------------------|------------------------|-----------------|------------|----------------|
| 19-Feb-2014  | 9911877                          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1013702 |                        | 73 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Coldness; Injection Site Pain | Epipen                           |                  |                    | S               |                           | 1:1000, 0.3 MI, 1 Time |                 | Mylan      |                |
|  | Actonel                          |                  |                    | C               | Oral                      | 150 Mg, Monthly        |                 |            |                |
|  | Metformin                        |                  |                    | C               | Oral                      | 500 Mg, 2tabs Bid      |                 |            |                |
|  | Lisinopril W/Hydrochlorothiazide |                  |                    | C               | Oral                      | 20/12.5 Mg             |                 |            |                |
|  | Simvastatin                      |                  |                    | C               | Oral                      | 40 Mg Daily            |                 |            |                |
|  | Finasteride                      |                  |                    | C               | Oral                      | 5 Mg Daily             |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911878                          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014061 |                        |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen                           |                  |                    | S               |                           | Unk                    |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911879                          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014062 |                        |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen                           |                  |                    | S               |                           | Unk                    |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911880                          | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014063 |                        |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product                              | Epipen                           |                  |                    | S               |                           | Unk                    |                 | Mylan      |                |

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|  |                |                  |                    |                 |                           |                      |                                 |                 |                |
|--|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|---------------------------------|-----------------|----------------|
| Administered   |                |                  |                    |                 |                           |                      |                                 |                 |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>                      | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014  | 9911881        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014155 |                      |                                 | Unknown         | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Injection Site Pain          | Epipen         |                  |                    |                 | S                         |                      | Unk                             |                 | Mylan          |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>                      | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014  | 9911882        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014156 |                      | 46 YR                           | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Expired Product Administered | Epipen         |                  |                    |                 | S                         | Unknown              | 0.3 Mg, As Needed               |                 | Mylan          |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>                      | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014  | 9911883        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014161 |                      |                                 | Unknown         | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>     |
| Expired Product Administered                                 | Epipen         |                  |                    |                 | S                         |                      | Unk                             |                 | Mylan          |
| <u>FDA Received Date</u>                                     | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>                      | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014  | 9911884        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014468 |                      | 3 YR                            | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product By Child                      | Epipen Jr      |                  |                    |                 | S                         | Subcutaneous         | 0.15 Mg, 1:2000, 0.3 MI, 1 Dose |                 | Mylan          |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|---------------------------|------------------------|-----------------|------------|----------------|
| 19-Feb-2014  | 9911885        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014471 |                        | 35 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Asthenia; Migraine; Nausea; Tremor           | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911886        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1014769 |                        | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child                                      | Epipen         |                  |                    | S               |                           | Unk                    |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911887        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1015091 |                        | 21 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Product Misuse   | Epipen         |                  |                    | S               |                           | Unk                    |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911888        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1015323 |                        | 36 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Pain In Extremity; Pain In Extremity; Tremor | Epipen Jr      |                  |                    | S               |                           | 1:2000, 0.3 MI, Single |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911889        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1015464 |                        |                 | Female     | USA            |

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| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|------------------|--------------------|-----------------|---------------------------|------------------------|-----------------|------------|----------------|
| Accidental Exposure To Product By Child; Product Quality Issue | Epipen         |                  |                    | S               | Unknown                   | 0.3 Mg, Unk            |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911890        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1015675 |                        | 62 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Effect Incomplete                         | Epipen         |                  |                    | S               | Intramuscular             |                        |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911891        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1015727 |                        |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain  | Epipen         |                  |                    | S               |                           | Unk                    |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911892        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016012 |                        | 61 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                                 | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, Daily          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911893        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016063 |                        | 8 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                                 | Epipen Jr      |                  |                    | S               | Parenteral                | 0.3 MI, Single, 1:2000 |                 | Mylan      |                |



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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|---------------------------|------------------------------|-----------------|------------|----------------|
| 19-Feb-2014  | 9911894        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016066 |                              | 30 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; Product Quality Issue                                 | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed (One Dose) |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911896        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016092 |                              |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Pain; Product Quality Issue  | Epipen         |                  |                    | S               |                           | Unk                          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911897        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016349 |                              |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen         |                  |                    | S               |                           | Unk                          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911898        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016427 |                              |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Product Quality Issue; Psychomotor Hyperactivity | Epipen         |                  |                    | S               |                           | Unk                          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911899        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016699 |                              | 5 YR            | Male       | USA            |

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| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
|--|-------------------|------------------|--------------------|-----------------|---------------------------|-------------------------|-----------------|------------|----------------|
| Accidental Exposure To Product By Child; Expired Product Administered; Nervousness           | Epipen            |                  |                    | S               |                           | Unk                     |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911900           | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016808 |                         |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen            |                  |                    | S               |                           | Unk                     |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911901           | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1016809 |                         | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered; Insomnia; Restless Legs Syndrome; Somnolence | Epipen            |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed       |                 | Mylan      |                |
|  | Epipen            |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed       |                 | Mylan      |                |
|  | Epipen            |                  |                    | S               |                           |                         |                 | Mylan      |                |
|  | Epipen            |                  |                    | S               |                           |                         |                 | Mylan      |                |
|  | Diphenhydramine   |                  |                    | S               |                           | 2 Tablets Taken Per Day |                 | Mylan      |                |
|  | Tramadol          |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |
|  | Valium            |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |
|  | Pravastatin       |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |
|  | Glyburide         |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |
|  | Strattera         |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |
|  | Vesicare          |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |
|  | Pulmicort         |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |
|  | Zolpidem Tartrate |                  |                    | C               | Unknown                   | Unk                     |                 |            |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911902        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1017488 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Haemorrhage; Injury Associated With Device; Oedema Peripheral; Product Quality Issue | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911903        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1017491 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Injury Associated With Device  | Epipen Jr      |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911904        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-2013S1017492 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
|   | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911905        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1017599 |                      | 58 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Injection Site Reaction  | Epipen         |                  |                    | S               |                           | 0.3 Mg Prn           |                 | Mylan      |                |

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|  |                |                  |                    |                 |                           |                      |                 |            |                |
|--|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Benadryl   |                |                  | C                  |                 |                           | Unk, Prn             |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911906        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1017812 |                      | 30 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Tremor   | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed    |                 | Mylan      |                |
|  | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed    |                 | Mylan      |                |
|  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
|  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911907        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1017853 |                      | 62 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Delivery Device Implantation; Drug Effect Incomplete                            | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed    |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911908        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-2013S1017896 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen         |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911909        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1017897 |                      | 33 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Energy Increased; Product Quality Issue; Therapeutic | Epipen         |                  |                    | S               |                           | 0.3 Mg, As Needed    |                 | Mylan      |                |
|  | Albuterol      |                  |                    | C               | Respiratory (inhalation)  | Unk                  |                 |            |                |

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|  |                     |                  |                    |                         |                           |                      |                 |            |                |
|--|---------------------|------------------|--------------------|-------------------------|---------------------------|----------------------|-----------------|------------|----------------|
| Response Unexpected  | Protonix            | C                | Oral               | Heartburn And Dyspepsia |                           |                      |                 |            |                |
|  | Hydrochlorothiazide | C                | Oral               | Unk                     |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911910             | NON-EXPEDITED    |                    |                         | US-MYLANLABS-2013S1018268 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Product Quality Issue                                      | Epipen              |                  |                    | S                       |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911911             | NON-EXPEDITED    |                    |                         | US-MYLANLABS-2013S1018269 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Hypoaesthesia | Epipen              |                  |                    | S                       | Unknown                   | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911912             | NON-EXPEDITED    |                    |                         | US-MYLANLABS-2013S1018459 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen              |                  |                    | S                       |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>         | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911913             | NON-EXPEDITED    |                    |                         | US-MYLANLABS-2013S1018547 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>             | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Tremor   | Epipen              |                  |                    | S                       |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911914        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1018548 |                      | 83 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Flushing; Pain  | Epipen         |                  |                    | S               | Intramuscular             | 0.30 Mg, Unk         |                 | Mylan      |                |
|   | Fish Oil       |                  |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911915        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1018870 |                      | 21 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthma; Expired Product Administered; Injection Site Pain; Vasoconstriction | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed    |                 | Mylan      |                |
|   | Albuterol      |                  |                    | C               | Respiratory (inhalation)  | Prn, Unk             |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911916        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1018871 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                           | 1 Time               |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911917        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-2013S1019097 |                      | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Chest Discomfort; Device Malfunction; Drug Ineffective; Pain In Extremity   | Epipen         |                  |                    | S               |                           | 0.3 Mg, Single       |                 | Mylan      |                |
|   | Benadryl       |                  |                    | C               | Oral                      | Unk                  |                 |            |                |
|   | Albuterol      |                  |                    | C               | Oral                      | Prn                  |                 |            |                |
|   | Effexor Sr     |                  |                    | C               | Oral                      | 300 Mg Am, 75 Mg At  |                 |            |                |

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|           |   |              |                          |
|-----------|---|--------------|--------------------------|
| Topamax   | C | Oral         | Noon                     |
| Lantus    | C | Subcutaneous | 50 Mg Am, 150 Mg Hs      |
| Nexium    | C | Oral         | 30 Units Am, 30 Units Pm |
| Ativan    | C | Oral         | Qam                      |
| Singulair | C | Oral         | 4mg, Unk; Tablet         |
| Trazodone | C | Oral         | Hs                       |
|           |   |              | 100 Mg, Hs               |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2014              | 9911918       | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-2013S1019161 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective      | Epipen         |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2014              | 9911919       | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1019233 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective; Myalgia | Epipen         |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 19-Feb-2014              | 9911920       | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1019234 |                      | 51 YR      | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Accidental Exposure To Product | Epipen         |              |            | S           | Intramuscular | 0.3 Mg, As Needed  |                 | Mylan      |
|                                | Zantac         |              |            | C           |               | 2x/Day             |                 |            |
|                                | Zyrtec         |              |            | C           |               | 2x/Day             |                 |            |
|                                | Prednisone     |              |            | C           |               | 1x/Day             |                 |            |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|---------------------------|-----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911921        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1019365 |                       | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Injury; Pain In Extremity; Product Quality Issue | Epipen         |                  |                    | S               |                           | 0.3 Mg, Unk           |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911923        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1019761 |                       | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                  |                    | S               | Intramuscular             | 0.3 Mg, As Needed     |                 | Mylan      |                |
|   | Zolpidem       |                  |                    | C               | Oral                      | 10 Mg, As Needed      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911924        | NON-EXPEDITED    |                    | HO              | US-MYLANLABS-2013S1019762 |                       | 63 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                  |                    | S               | Unknown                   | 0.3 Mg, As Needed     |                 | Mylan      |                |
|   | Metformin      |                  |                    | C               | Oral                      | 500 Mg, Unk           |                 |            |                |
|   | Lisinopril     |                  |                    | C               | Oral                      | Unk                   |                 |            |                |
|   | Gabapentin     |                  |                    | C               | Oral                      | Hs                    |                 |            |                |
|   | Trazodone      |                  |                    | C               | Oral                      | Hs                    |                 |            |                |
|   | Benadryl       |                  |                    | C               |                           | 25 Mgx1 Approx <1 Min |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911925        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1019961 |                       |                 | Female     | USA            |



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| <u>Preferred Term</u>                      | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------|------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Injection Site<br>Haemorrhage              | Epipen             |                  |                    | S               |                               |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                | 9911926            | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1020149 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                             | Epipen 2-Pak       |                  |                    | S               |                               |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                | 9911927            | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1020182 |                      | 4 YR            | Male       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product By Child | Epipen Jr          |                  |                    | S               | Subcutaneous                  | 0.15 Mg, As Needed   |                 | Mylan      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                | 9911928            | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-<br>2013S1020217 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                           | Epipen             |                  |                    | S               |                               | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>      | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                | 9911929            | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1020300 |                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>     | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                             | Epipen 2-Pak       |                  |                    | S               | Intramuscular                 |                      |                 | Mylan      |                |
|  | Benadryl           |                  |                    | C               |                               |                      |                 |            |                |
|  | Allergy Medication |                  |                    | C               |                               |                      |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014  | 9911930        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1020355 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Abnormal;<br>Erythema; Headache;<br>Oedema Peripheral;<br>Swelling Face   | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911931        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1020504 |                      | 63 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen         |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
|  | Epipen         |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911932        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1020515 |                      | 42 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered;<br>Hypoaesthesia; Injection Site Coldness; Injection Site Hypoaesthesia; Peripheral Coldness | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911933        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1020759 |                      | 72 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug   | Epipen 2-Pak   |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |

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## Freedom of Information Act (FOIA)

### Detailed Report

Ineffective

| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014                                    | 9911935        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1021022 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                 | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                    | 9911936        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1021732 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Dyspnoea; Tongue Oedema        | Epipen 2-Pak   |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
|  | Epipen 2-Pak   |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                    | 9911937        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1021824 |                      | 32 YR           | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                 | Epipen         |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
|  | Cefdinir       |                  |                    | C               | Oral                      |                      |                 |            |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                    | 9911938        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1021876 |                      | 273 DAY         | Male       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; No Adverse Event | Epipen Jr      |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                    | 9911939        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1021884 |                      |                 | Female     | USA            |

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| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product         | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                            | 9911940        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1022286 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product         | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                            | 9911943        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1022608 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                         | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                            | 9911944        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1022655 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Incorrect Drug Administration Duration | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                            | 9911945        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1023131 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product         | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                            | 9911946        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-             |                      |                 | Female     | USA            |

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2013S1023394

| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--|------------------|--------------------|-----------------------|---------------------------|----------------------|-----------------|------------|----------------|
| Nightmare  | Epipen   |                  |                    | S                     |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911947  | NON-EXPEDITED    |                    |                       | US-MYLANLABS-2013S1023441 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Hypoaesthesia; Skin Discolouration | Epipen   |                  |                    | S                     |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911948  | NON-EXPEDITED    |                    |                       | US-MYLANLABS-2013S1023501 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Needle Issue  | Epipen<br>Proair Hfa<br>Symbicort<br>Spiriva<br>Lyrica |                  |                    | S<br>C<br>C<br>C<br>C |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u>       | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911949  | NON-EXPEDITED    |                    |                       | US-MYLANLABS-2013S1023539 |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>   | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>           | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen   |                  |                    | S                     |                           |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014  | 9911950        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1023556 |                      | 73 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Muscle Spasms  | Epipen 2-Pak   |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911951        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1023981 |                      | 19 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Dizziness; Injection Site Haemorrhage  | Epipen 2-Pak   |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911952        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1024014 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Unevaluable Event  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911953        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1024019 |                      | 70 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Drug Ineffective; Expired Product Administered; Hypersensitivity; Injection Site Haemorrhage | Epipen         |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014  | 9911954                        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1024029 |                      | 47 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Device Malfunction; Injury Associated With Device  | Epipen 2-Pak Bystolic Singular |                  |                    | S<br>C<br>C     | Oral<br>Oral              |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911955                        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1024034 |                      | 39 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia; Injection Site Discolouration; Injection Site Hypoaesthesia; Injection Site Pain; Skin Discolouration | Epipen                         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911957                        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1024123 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Hypersensitivity; Insomnia   | Epipen Corticosteroid Nos      |                  |                    | S<br>S          |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911958                        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1024137 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Hot Flush; Hypersensitivity  | Epipen                         |                  |                    | S               | Intramuscular             |                      |                 | Mylan      |                |

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|                                   |                         |                           |                             |                          |                               |                               |                             |                          |                         |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Benadryl                          |                         |                           | C                           |                          | Oral                          |                               | Takes Prn.                  |                          |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911959                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1024223     |                               |                             | Unknown                  | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Accidental Exposure To Product    | Epipen                  |                           |                             |                          | S                             |                               |                             |                          | Mylan                   |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911960                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1024382     |                               |                             | Female                   | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Tremor                            | Epipen                  |                           |                             |                          | S                             |                               |                             |                          | Mylan                   |
|                                   | Benadryl                |                           |                             |                          | S                             |                               |                             |                          | Mylan                   |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911961                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1024582     |                               |                             | Male                     | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Injection Site Pain               | Epipen                  |                           |                             |                          | S                             |                               |                             |                          | Mylan                   |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911962                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1024656     |                               |                             | Female                   | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Injection Site Bruising           | Epipen                  |                           |                             |                          | S                             |                               |                             |                          | Mylan                   |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911963                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1024792     |                               |                             | Unknown                  | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |



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|  |  |                  |                    |                 |                               |                      |                 |            |                |
|--|--|------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Injection Site<br>Haemorrhage  | Epipen                                     |                  | S                  |                 |                               |                      |                 |            | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911964                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1024795 |                      | 42 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen 2-Pak                               |                  |                    | S               | Intramuscular                 |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911965                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1024897 |                      | 46 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Screen Positive   | Epipen<br>Trazodone<br>Claritin /00917501/ |                  |                    | S<br>C<br>C     | Intramuscular                 |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911966                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1025166 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product  | Epipen Jr                                  |                  |                    | S               |                               |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014  | 9911967                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2013S1025312 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injection Site<br>Pain; Pain In Extremity | Epipen                                     |                  |                    | S               |                               |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911968        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1025390 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; No Adverse Event      | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911969        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1025425 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; No Adverse Event      | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911970        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1025441 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Injury | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911971        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1025447 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Malaise   | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911972        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1025682 |                      |                 | Male       | USA            |

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| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Pain                   | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911973        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1025684 |                      | 57 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Discolouration; Pallor | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911974        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1025724 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911975        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1026184 |                      | 74 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911976        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1026315 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------------|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014                     | 9911977        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1026502 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity           | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                     | 9911978        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1026647 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising         | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                     | 9911979        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1026649 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                     | 9911980        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1026701 |                      | 45 YR           | Male       | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Arthropod Sting; Device Failure | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>        | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                     | 9911981        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1026824 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>           | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911982        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1027184 |                      | 7 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child   | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911983        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1027307 |                      | 67 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Hypoaesthesia; Injection Site Pain | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911984        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1027394 |                      | 6 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911985        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1027527 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Discomfort; Injection Site Pain  | Epipen         |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911986        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1027577 |                      |                 | Male       | USA            |

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| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product    | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911988                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1028053     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Injury             | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911990                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1028465     |                               | 40 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                    | Epipen                  |                           |                             | S                        | Intramuscular                 |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911991                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1028581     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product    | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911992                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1028582     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product    | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Feb-2014                       | 9911993                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1028598     |                               |                          | Female              | USA                     |

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| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911994        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1028608  |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911995        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1028609  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Device Used; Injection Site Haemorrhage | Epipen         |                  |                    | S               |                            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911996        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2013S1028796  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Administered At Inappropriate Site                                      | Epipen         |                  |                    | S               |                            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911997        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-PF-2012286586 |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen         |                  |                    | S               |                            | 1 Df, As Needed      |                 | Mylan      |                |
|   | Epipen         |                  |                    | S               |                            | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9911998        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-PF-2012300213 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                                    | Epipen         |                  |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9911999        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2012330958 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Rate Increased                                | Epipen         |                  |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9912000        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013004511 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain | Epipen         |                  |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9912001        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013004520 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                      | Epipen         |                  |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9912002        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013014705 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|   |                |                  |                    |                 |                            |                      |                 |            |                |



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|   |                |                  |                    |                 |                            |                      |                    |                 |                |
|---|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|--------------------|-----------------|----------------|
| Accidental Exposure To Product                        | Epipen         |                  | S                  |                 |                            | Unk                  |                    |                 | Mylan          |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9912003        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-PF-2013052743 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Dizziness             | Epipen Jr      |                  |                    | S               |                            |                      | 0.15 Mg            |                 | Mylan          |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9912004        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013061499 |                      |                    | Male            | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Product Quality Issue | Epipen         |                  |                    | S               |                            |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9912005        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013066871 |                      |                    | Male            | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Product Label Issue   | Epipen         |                  |                    | S               |                            |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>                              | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014   | 9912006        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013201470 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product By Child               | Epipen         |                  |                    | S               | Unknown                    |                      | 0.3 Mg, Unk        |                 | Mylan          |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
|--|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|--------------------|-----------------|----------------|
| 19-Feb-2014  | 9912007        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-PF-2013214319 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective; Product Quality Issue  | Epipen         |                  |                    |                 | S                          |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014  | 9912008        | NON-EXPEDITED    |                    | DE              | US-MYLANLABS-PF-2013226310 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective   | Epipen         |                  |                    |                 | S                          |                      | 3 Df, Unk          |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014  | 9912009        | NON-EXPEDITED    |                    | OT              | US-MYLANLABS-PF-2013272180 |                      | 45 YR              | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective; Product Packaging Quantity Issue   | Epipen         |                  |                    |                 | S                          | Intramuscular        | 0.3 Mg, Unk        |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 19-Feb-2014  | 9912010        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013274061 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                  | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>                | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Paraesthesia; Injury Associated With Device; Paraesthesia | Epipen Jr      |                  |                    |                 | S                          |                      | Unk                |                 | Mylan          |
|  | Allegra        |                  |                    |                 | C                          |                      |                    |                 |                |
|  | Singulair      |                  |                    |                 | C                          |                      |                    |                 |                |
|  | Avapro         |                  |                    |                 | C                          |                      |                    |                 |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|--|---------------------|------------------|--------------------|-----------------|----------------------------|--|-----------------|----------------|----------------|
| 19-Feb-2014  | 9912012             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013279545 |  |                 | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>     |                |
| Feeling Abnormal; Flushing; Nausea   | Epipen<br>Benadryl  |                  |                    | S<br>C          | Intramuscular              | 0.3 Mg, Unk                                |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9912013             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013279546 |  |                 | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Product Quality Issue  | Epipen<br>Epipen    |                  |                    | S<br>S          |                            | Unk  |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9912014             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013279637 |  | 35 YR           | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Injection Site Paraesthesia  | Epipen Jr           |                  |                    | S               | Intramuscular              | 0.15 Mg, Unk                               |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>                       | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 19-Feb-2014  | 9912015             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013282050 |  | 40 YR           | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>                         | <u>Duration</u> | <u>Mfr</u>     |                |
| Dyspnoea; Injection Site Nodule; Injection Site Pain; Palpitations; Product Administered At Inappropriate Site | Epipen<br>Estrogens |                  |                    | S<br>C          |                            | 0.3 Mg, Unk<br>Over The Counter Medication |                 | Mylan          |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014   | 9912016        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013286325 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Discolouration; Injection Site Pain; Injection Site Pallor | Epipen         |                  |                    | S               |                            | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9912017        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013286360 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               | Intramuscular              | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9912018        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013293287 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014   | 9912019        | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013293288 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen         |                  |                    | S               | Unknown                    | 0.3 Mg, Unk          |                 | Mylan      |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 19-Feb-2014                                    | 9912020        | NON-EXPEDITED      |                    |                 | US-MYLANLABS-PF-2013293300 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                 | Epipen         |                    |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                    | 9912021        | NON-EXPEDITED      |                    |                 | US-MYLANLABS-PF-2013294876 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain                            | Epipen         |                    |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Feb-2014                                    | 9912022        | NON-EXPEDITED      |                    |                 | US-MYLANLABS-PF-2013294958 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia  | Epipen         |                    |                    | S               |                            | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Feb-2014                                    | 9914064        | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2014S1003389  |                      | 7 YR            | Male       | GBR            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Wound | Epipen         |                    |                    | S               | Intramuscular              |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Feb-2014                                    | 9921948        | DIRECT             |                    | HO, LT          |                            |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Apnoea; Drug Monitoring                        | Epipen         |                    |                    | S               |                            |                      |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Procedure Not Performed;  
Dyspnoea; Inappropriate  
Schedule Of Drug  
Administration; Loss Of  
Consciousness; Pulse  
Absent; Underdose

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 07-Mar-2014                       | 9981376                | EXPEDITED (15-DAY)        |                             | OT                       | FR-MYLANLABS-2014S1004944     |                               | 7 YR                | Male                | FRA                     |

| <a href="#">Preferred Term</a>                           | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure; Wrong Technique In Product Usage Process | Epipen                  |                       |                     | S                    |                       |                             |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Mar-2014                       | 9995761                | DIRECT                    | Y                           | OT                       |                               |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a>                    | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Malfunction; Injury Associated With Device | Epipen                  |                       |                     | S                    |                       |                             |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Mar-2014                       | 10006021               | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2014S1004916     |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Effect Decreased; Expired Product Administered | Epipen                  |                       |                     | S                    |                       |                             |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Mar-2014                       | 10008394               | EXPEDITED (15-DAY)        |                             | OT                       | SE-MYLANLABS-2014S1005559     |                               |                     | Female              | SWE                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure                 | Epipen                  |                       |                     | S                    |                       |                             |                          | Mylan               |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Mar-2014                                      | 10021420       | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2014S1006079 |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; No Adverse Event   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Mar-2014                                      | 10038369       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1005946 |                      | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Loss Of Consciousness            | Epipen 2-Pak   |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Mar-2014                                      | 10039183       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1006018 |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                   | Epipen 2-Pak   |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Mar-2014                                      | 10048603       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1006689 |                      | 15 YR           | Male       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Injection Site Laceration; Needle Issue | Epipen 2-Pak   |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
|  | Xopenex        |                    |                    | C               | Respiratory (inhalation)  |                      |                 |            |                |
|  | Singulair      |                    |                    | C               | Oral                      | Taken For Years      |                 |            |                |
|  | Pulmicort      |                    |                    | C               | Respiratory (inhalation)  | Taken For Years      |                 |            |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|------------|----------------|
| 31-Mar-2014   | 10048672       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1004047             |                      | 61 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Incorrect Dose Administered; Stress; Wrong Technique In Product Usage Process | Epipen 2-Pak   |                    |                    | S               | Intramuscular                         |                      |                 | Mylan      |                |
|   | Epipen 2-Pak   |                    |                    | S               | Intramuscular                         |                      |                 | Mylan      |                |
|   | Epipen 2-Pak   |                    |                    | S               | Intramuscular                         |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Apr-2014   | 10064470       | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2014S1006963             |                      |                 | Female     | AUS            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Product Package Associated Injury                      | Epipen         |                    |                    | S               |                                       |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Apr-2014   | 10073664       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2014102042              |                      | 70 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fatigue; Injection Site Pain; Nervousness                                     | Epipen         |                    |                    | S               | Intramuscular                         |                      |                 | Pfizer     |                |
|   | Solu-Medrol    |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 | Pfizer     |                |
|   | Prednisone     |                    |                    | S               | Oral                                  |                      |                 |            |                |
|   | Lantus         |                    |                    | C               | Subcutaneous                          |                      |                 |            |                |
|   | Novolog        |                    |                    | C               | Subcutaneous                          |                      |                 |            |                |
|   | Keppra         |                    |                    | C               | Oral                                  |                      |                 |            |                |
|   | Metformin      |                    |                    | C               | Oral                                  |                      |                 |            |                |
|   | Lipitor        |                    |                    | C               | Oral                                  |                      |                 |            |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 14-Apr-2014   | 10074611       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1008153 |                      | 39 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen 2-Pak   |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Apr-2014   | 10077848       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1008463 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Bruising; Injection Site Pain                                      | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Apr-2014   | 10079920       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1008306 |                      | 58 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen 2-Pak   |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Apr-2014   | 10089352       | EXPEDITED (15-DAY) |                    | HO              | AU-MYLANLABS-2014S1008188 |                      |                 | Male       | AUS            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Apparent Death; Asphyxia; Cardiac Arrest; Fall; Hypersensitivity; Needle Issue; Pharyngeal Oedema | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-May-2014   | 10159806       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2014S1010067 |                      | 89 YR           | Male       | JPN            |

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| <u>Preferred Term</u>                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|-----------------------------|--------------------|--------------------|-----------------|--|----------------------|-----------------|------------|----------------|
| Injection Site Pain;<br>Product Quality Issue              | Epipen<br>Bosmin /00003901/ |                    |                    | S<br>C          | Intramuscular                            | 0.3 Mg, Daily        |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-May-2014  | 10170269                    | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-<br>2014S1010125            |                      | 4 YR            | Male       | CAN            |
| <u>Preferred Term</u>                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product By Child; Limb<br>Injury | Epipen                      |                    |                    | S               |  |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-May-2014  | 10176732                    | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-<br>2014S1010674            |                      | 59 YR           | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen 2-Pak                |                    |                    | S               | Intramuscular                            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-May-2014  | 10191271                    | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-<br>2014S1011922            |                      | 70 YR           | Female     | DEU            |
| <u>Preferred Term</u>                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen                      |                    |                    | S               | Intravenous (not<br>otherwise specified) |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-May-2014  | 10200177                    | EXPEDITED (15-DAY) |                    | HO, OT          | SE-MYLANLABS-<br>2014S1011924            |                      | 80 YR           | Male       | SWE            |
| <u>Preferred Term</u>                                      | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug<br>Ineffective                        | Epipen                      |                    |                    | S               |  |                      |                 | Mylan      |                |

# FDA Adverse Event Reporting System

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| <a href="#">FDA Received Date</a>                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 11-Jun-2014  | 10230606                | EXPEDITED (15-DAY)        |                             | HO                       | CA-MYLANLABS-2014S1012634     |                               |                          | Female              | CAN                     |
| <a href="#">Preferred Term</a>                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Jun-2014  | 10250460                | DIRECT                    |                             |                          |                               |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Dispensing Error; Intercepted Drug Dispensing Error | Epi Pen                 |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jun-2014  | 9681902                 | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2013S1025073     |                               | 68 YR                    | Male                | JPN                     |
| <a href="#">Preferred Term</a>                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anaemia; Dyspnoea; Haemorrhage                           | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| Subcutaneous; Injection                                  | Norvasc                 |                           |                             | C                        | Oral                          |                               |                          |                     |                         |
| Site Pain; Oedema  | Diovan                  |                           |                             | C                        | Oral                          |                               |                          |                     |                         |
| Peripheral; Oral Pain                                    |                         |                           |                             |                          |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jun-2014  | 9695174                 | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2013S1025537     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>                           | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered                             | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                        | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jun-2014  | 10257461                | DIRECT                    |                             | OT                       |                               |                               | 49 YR                    | Female              | USA                     |

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| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
|---|-----------------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------------------|-----------------|------------|----------------|
| Discomfort; Gait Disturbance; Gait Inability; Injection Site Pain; Injection Site Swelling; Muscle Spasms | Epi-Pen Autoinjector 0.3 Mg |                    |                    | S               |                           | 0.3mg, As Needed, Into The Muscle |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Jun-2014   | 10256799                    | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2014S1014415 |                                   |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction; Dyspnoea; Injury Associated With Device; Pharyngeal Oedema; Swollen Tongue            | Epipen                      |                    |                    | S               | Intramuscular             |                                   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Jun-2014   | 10233878                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1013506 |                                   | 28 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Ischaemia                    | Epipen 2-Pak                |                    |                    | S               |                           |                                   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2014   | 10273594                    | DIRECT             | Y                  | OT              |                           |                                   | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain; Cough; Dysphonia; Food Allergy; Injury Associated With Device; Urticaria; Wheezing        | Epipen Jr                   |                    |                    | S               |                           |                                   |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|---|------------------------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------------------|-----------------|----------------|----------------|
| 02-Jul-2014   | 10274908                           | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1015316 |                                   | 57 YR           | Female         | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>     |                |
| Drug Effect Decreased; Feeling Jittery; Heart Rate Decreased; Urticaria           | Epipen 2-Pak                       |                    |                    | S               | Intramuscular             |                                   |                 | Mylan          |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 08-Jul-2014   | 10283757                           | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1015855 |                                   | 12 YR           | Female         | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>     |                |
| Device Failure; Drug Ineffective; Dyspnoea; Pharyngeal Oedema                     | Epipen 2-Pak<br>Prednisone         |                    |                    | S<br>C          | Intramuscular             |                                   |                 | Mylan          |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 08-Jul-2014   | 10285021                           | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1015680 |                                   | 5 YR            | Male           | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>     |                |
| Anaphylactic Reaction; Drug Effect Decreased; Injection Site Injury; Needle Issue | Epipen Jr 2-Pak<br>Epipen Jr 2-Pak |                    |                    | S<br>S          |                           |                                   |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>              | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 11-Jul-2014   | 10305805                           | DIRECT             |                    | LT, OT          |                           |                                   | 52 YR           | Female         | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                | <u>Duration</u> | <u>Mfr</u>     |                |
| Dyspnoea; Hypoaesthesia Eye   | Epipen                             |                    |                    | S               | Intramuscular             | Autoinjector Once Into The Muscle |                 | Sanofi         |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-----------------|--------------------|--------------------|-----------------|----------------------------|----------------------|-----------------|------------|----------------|
| 14-Jul-2014  | 10143006        | EXPEDITED (15-DAY) |                    | DE              | US-MYLANLABS-PF-2013221268 |                      | 13 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Drug Ineffective; Dyspnoea; Laryngeal Oedema; Respiratory Arrest; Vomiting | Epipen          |                    |                    | S               |                            | 3 Epy Pens           |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Jul-2014  | 10273180        | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-2014S1015415  |                      | 2 YR            | Male       | BRA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective; No Adverse Event   | Epipen          |                    |                    | S               |                            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Jul-2014  | 10302880        | EXPEDITED (15-DAY) |                    | OT              | ES-MYLANLABS-2014S1014886  |                      | 11 YR           | Female     | ESP            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen          |                    |                    | S               |                            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jul-2014  | 9899483         | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1002978  |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device  | Epipen Jr 2-Pak |                    |                    | S               | Intramuscular              |                      |                 | Mylan      |                |
|  | Epipen Jr 2-Pak |                    |                    | S               | Intramuscular              |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|--|------------------------------|--------------------|--------------------|-----------------|------------------------------|-------------------------|-----------------|----------------|----------------|
| 16-Jul-2014  | 10215239                     | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1012450    |                         | 33 YR           | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>     |                |
| Device Failure; Dyspnoea; Pharyngeal Oedema; Tremor  | Epipen 2-Pak<br>Epipen 2-Pak |                    |                    | S<br>S          |                              |                         |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Jul-2014  | 10276583                     | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2014S1015101    |                         | 30 YR           | Male           | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>     |                |
| Anaphylactic Reaction; Drug Dispensing Error; Drug Ineffective; Wrong Technique In Product Usage Process | Epipen                       |                    |                    | S               |                              |                         |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Jul-2014  | 10309460                     | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1016648    |                         |                 | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Limb Injury; Wrong Technique In Product Usage Process                    | Epipen                       |                    |                    | S               |                              |                         |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Jul-2014  | 10312147                     | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1016326    |                         | 77 YR           | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>     |                |
| Device Failure; Expired Product Administered   | Epipen 2-Pak<br>Albuterol    |                    |                    | S<br>C          | Intramuscular<br>Respiratory |                         |                 | Mylan          |                |
|  |                              |                    |                    |                 |                              | Use 2 To 3 Times Daily. |                 |                |                |

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(inhalation)

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 18-Jul-2014              | 10313751      | EXPEDITED (15-DAY) |                    | HO, OT          | US-SHIRE-<br>US201403903 |                      | 53 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>             | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective;<br>Dyspnoea; Hereditary<br>Angioedema; Rash;<br>Wheezing | Firazyr                    |              |            | S           | Subcutaneous | 30 Mg, As Req'D    |                 | Shire      |
|  | Epipen                     |              |            | S           | Unknown      | Unk, One Dose      |                 |            |
|  | Epipen                     |              |            | S           | Unknown      | Unk, Unknown       |                 |            |
|  | Other Therapeutic Products |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Prednisone                 |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Kalbitor                   |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Albuterol Hfa              |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Pepcid /00305201/          |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Dyazide                    |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Potassium Cl               |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Clonazepam                 |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Zyrtec                     |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Armour Thyroid             |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Acidophilus                |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Magnesium                  |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Benadryl /00000402/        |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Ibuprofen                  |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Tylenol /00020001/         |              |            | C           | Unknown      | Unk, Unknown       |                 |            |
|  | Vitamins Nos               |              |            | C           | Unknown      | Unk, Unknown       |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 23-Jul-2014              | 10337315      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2014S1017031 |                      | 59 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|   |                             |                    |                    |                 |                           |                      |                 |            |                |
|---|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen 2-Pak                |                    |                    | S               |                           |                      |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Jul-2014   | 10359261                    | DIRECT             |                    |                 |                           |                      | 1 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device; Panic Reaction; Skin Discolouration; Wrong Patient Received Medication | Epi-Pen Jr                  |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Aug-2014   | 10365132                    | DIRECT             |                    | OT              |                           |                      | 4 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Heart Rate Increased; Laceration; Respiratory Rate Increased                                 | Epipen Jr                   |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Aug-2014   | 10368752                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1017771 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | .3 Mg,Prn            |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Aug-2014   | 10368811                    | EXPEDITED (15-DAY) |                    | DE              | GB-MYLAN-2014M1000042     |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypersensitivity  | Epipen Auto-Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 |            | Mylan          |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 08-Aug-2014  | 10375159             | DIRECT             |                    |                 |                           |                      | 3 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Circumstance Or Information Capable Of Leading To Device Use Error; Haemorrhage; Injury Associated With Device; Palpitations | Epipen               |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Aug-2014  | 10380875             | DIRECT             | Y                  | OT              |                           |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fatigue; Laceration; Urticaria   | Epipen Jr            |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Aug-2014  | 10381533             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1000469 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Hypokalaemia; Therapeutic Response Unexpected; Vasoconstriction  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Aug-2014  | 10394539             | EXPEDITED (15-DAY) |                    | LT              | CA-MYLANLABS-2014S1017901 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                       | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 22-Aug-2014  | 10337332                           | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2014S1017260 |                      |                 | Male       | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue                                   | Epipen                             |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Aug-2014  | 10403217                           | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2014M1002017 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; Feeling Abnormal                 | Epipen                             |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Aug-2014  | 10406154                           | DIRECT             |                    |                 |                           |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Dispensing Error  | Epipen<br>Epipen Jr. Auto-Injector |                    |                    | S<br>S          |                           |                      |                 |            |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Aug-2014  | 10406581                           | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1001490 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective; Pharyngeal Oedema; Urticaria | Epipen Auto-Injector               |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Aug-2014  | 10373107                           | EXPEDITED (15-DAY) |                    | DE              | US-MYLANLABS-2014M1000582 |                      |                 | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Drug Ineffective; Expired Product Administered                           | Epipen Auto-Injector    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Aug-2014  | 10411302                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2014M1001935     |                               |                          | Unknown             | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered; Feeling Abnormal                           | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Aug-2014  | 10417315                | EXPEDITED (15-DAY)        |                             | HO                       | BE-MYLAN-2013S1023101         |                               |                          | Unknown             | BEL                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Paraesthesia; Wrong Technique In Product Usage Process | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
|  | Adrenaline              |                           |                             | S                        |                               | .8 Mg,Unk                     |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Aug-2014  | 10417316                | EXPEDITED (15-DAY)        |                             | LT                       | DK-MYLAN-2013S1001201         |                               |                          | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Ineffective   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Sep-2014  | 10429991                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2014M1002420     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 MI, Qd                    |                          | Mylan               |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 08-Sep-2014   | 10440715                               | DIRECT             | Y                  |                 |                               |                      | 40 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Incorrect Dose<br>Administered By Device;<br>Needle Issue   | Epi Pen<br>Prednisone<br>Doxy          |                    |                    | S<br>C<br>C     |                               |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Sep-2014   | 10441808                               | EXPEDITED (15-DAY) |                    | DE              | US-MYLANLABS-<br>2014M1002941 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Product Misuse  | Epipen Auto-Injector                   |                    |                    | S               |                               |                      |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Sep-2014   | 10441810                               | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2014M1002878 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction;<br>Device Failure; Drug<br>Ineffective   | Epipen Auto-Injector<br>Antiepileptics |                    |                    | S<br>C          | Intramuscular                 | 0.3 Mg, Prn          |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Sep-2014   | 10369299                               | EXPEDITED (15-DAY) |                    | OT              | JP-MYLAN-<br>\$E2B0000047335  |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product By Child; Gait<br>Disturbance; Injection Site<br>Pain; Restlessness | Epipen Injection 0.15mg                |                    |                    | S               | Subcutaneous                  | .15 Mg,Unk           |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Sep-2014   | 10450765                               | EXPEDITED (15-DAY) |                    | HO              | GB-MYLAN-<br>2014M1004170     |                      |                 | Unknown    | GBR            |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-----------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Drug Ineffective  | Epipen Auto-Injector 0.3 Mg |                           |                             | S                        |                               | Separate Dosages: 1           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Sep-2014   | 10478391                    | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2014M1004716     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Ineffective; Pharyngeal Oedema; Swollen Tongue   | Epipen Auto-Injector        |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Oct-2014   | 10423652                    | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2014M1002752     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Expired Product Administered; Heart Rate Increased; Injection Site Erythema; Injection Site Pain; Injection Site Swelling | Epipen                      |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Oct-2014   | 10507403                    | EXPEDITED (15-DAY)        |                             | OT                       | SE-MYLANLABS-2014M1005415     |                               |                          | Unknown             | SWE                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>     | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Adverse Event; Reaction To Excipient  | Epipen                      |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
|   | Anapen /00003901/           |                           |                             | S                        |                               |                               |                          |                     |                         |
|   | Thacapzol                   |                           |                             | S                        |                               | Unk                           |                          |                     |                         |
|   | Metoprolol                  |                           |                             | C                        |                               |                               |                          |                     |                         |
|   | Metoprolol                  |                           |                             | C                        |                               |                               |                          |                     |                         |
|   | Paracetamol                 |                           |                             | C                        |                               |                               |                          |                     |                         |
|   | Prednisolone                |                           |                             | C                        |                               |                               |                          |                     |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |  |                    |                    |                 |                           |                      |                 |            |                |
|--|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Felodipine   |  |                    | C                  |                 |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Oct-2014  | 10507886                                   | EXPEDITED (15-DAY) |                    | OT              | BE-MYLANLABS-2014M1005238 |                      |                 | Unknown    | BEL            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen                                     |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Oct-2014  | 10521488                                   | DIRECT             | Y                  |                 |                           |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device; Skin Discolouration; Vasoconstriction | Epipen (Epinephrine) Phentolamine Mesylate |                    |                    | S<br>S          |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Oct-2014  | 10521642                                   | DIRECT             | Y                  |                 |                           |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Laceration; Needle Issue; Scar; Wrong Technique In Product Usage Process                    | Epipen Jr                                  |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Oct-2014  | 10530920                                   | DIRECT             | Y                  |                 |                           |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Urticaria   | Epipen Jr                                  |                    |                    | S               |                           |                      |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 21-Oct-2014               | 10532720                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1007007 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure            | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Oct-2014               | 10516184                    | EXPEDITED (15-DAY) |                    | HO              | GB-MYLANLABS-2014M1007199 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Underdose | Epipen Auto-Injector 0.3 Mg |                    |                    | S               |                           | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Oct-2014               | 10465106                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1004212 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure            | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|                           | Epipen Auto-Injector        |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Oct-2014               | 10538179                    | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2014M1007824 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypersensitivity          | Epipen                      |                    |                    | S               |                           |                      |                 | Mylan      |                |
|                           | Thacapzol                   |                    |                    | S               |                           | Unk                  |                 |            |                |
|                           | Prednisolone                |                    |                    | C               |                           | 5 Mg, Qd             |                 |            |                |
|                           | Prednisolone                |                    |                    | C               |                           |                      |                 |            |                |
|                           | Cortisone                   |                    |                    | C               |                           |                      |                 |            |                |
|                           | Anapen /00003901/           |                    |                    | C               |                           |                      |                 |            |                |
|                           | Selokeen                    |                    |                    | C               |                           |                      |                 |            |                |
|                           | Selokeen                    |                    |                    | C               |                           |                      |                 |            |                |
|                           | Felodipine                  |                    |                    | C               |                           |                      |                 |            |                |



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| Paracetamol   |                      |                    | C                  |                 |                           |                      |                 |            |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2014   | 10548915             | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2014M1008081 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injury Associated With Device                        | Epipen Jr            |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2014   | 10548949             | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2014M1008084 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Oct-2014   | 10552860             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1007832 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission; Dysphagia   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Oct-2014   | 10552884             | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2014M1008070 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; Incorrect Dose Administered; Injection Site Injury; Tachycardia | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Albuterol /00139501/ |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Adderall             |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Singulair            |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Zyrtec               |                    |                    | C               |                           | Unk                  |                 |            |                |

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| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------------|-----------------|------------|----------------|
| 30-Oct-2014  | 10337323             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1017245 |                                 |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered | Epipen Auto-Injector |                    |                    | S               |                           | .3 Mg, Once                     |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Nov-2014  | 10561239             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1008590 |                                 |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn                     |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Nov-2014  | 10561265             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1009005 |                                 |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn                     |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Nov-2014  | 10563792             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2014258561  |                                 | 61 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety;                     | Epipen               |                    |                    | S               |                           | 0.3 Mg, Prn (Take 2 Injections) |                 | Pfizer     |                |
| Dizziness; Drug Interaction; Dyspepsia;                      | Levothyroxine Sodium |                    |                    | S               |                           | Unk                             |                 | Pfizer     |                |
| Dyspnoea; General Physical Health                            | Exforge              |                    |                    | C               |                           | Unk                             |                 |            |                |
| Deterioration; Headache;                                     | Protonix             |                    |                    | C               |                           | Unk                             |                 |            |                |
| Heart Rate Increased; Hyperhidrosis;                         | Estrogens            |                    |                    | C               |                           | Unk                             |                 |            |                |

# FDA Adverse Event Reporting System

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Palpitations; Pharyngeal Oedema; Swollen Tongue; Tremor

Prednisone

C

Unk

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2014              | 10437621      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1002888 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Anal Incontinence;  | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Mylan      |
| Anxiety; Asthenia; Body Temperature Increased;  | Epipen Auto-Injector |              |            | S           |               |                    |                 | Mylan      |
| Chills; Confusional State; Feeling Abnormal; Feeling Cold; Hyperhidrosis; Livedo Reticularis; | Ophthalmologicals    |              |            | C           |               | Unk                |                 |            |
| Nausea; Nervousness; Presyncope; Pruritus; Retching; Tremor                                   | Benadryl /00000402/  |              |            | C           |               | Unk                |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 05-Nov-2014              | 10567239      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2014M1009620 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product By Child; Emotional Distress; Injection Site Pain | Epipen Auto-Injector 0.3 Mg |              |            | S           |              | Unk Mg, Unk        |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 07-Nov-2014              | 10571593      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1009084 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure; Drug Dose Omission | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Mylan      |

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### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------------|-----------------|------------|----------------|
| 07-Nov-2014  | 10571604                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1004141 |                                 |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Dizziness; Drug Interaction; Dyspepsia; Dyspnoea; Headache; Heart Rate Increased; Hyperhidrosis; Palpitations; Pharyngeal Oedema; Swollen Tongue; Tremor; Unevaluable Event | Epipen Auto-Injector     |                    |                    | S               |                           | 0.3 Mg, Prn (Take 2 Injections) |                 | Mylan      |                |
|  | Exforge                  |                    |                    | C               |                           | Unk                             |                 |            |                |
|  | Protonix                 |                    |                    | C               |                           | Unk                             |                 |            |                |
|  | Estrogens                |                    |                    | C               |                           | Unk                             |                 |            |                |
|  | Levothyroxine            |                    |                    | C               |                           | Unk                             |                 |            |                |
|  | Prednisone               |                    |                    | C               |                           | Unk                             |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Nov-2014  | 10574703                 | EXPEDITED (15-DAY) |                    | DS, OT          | US-MYLANLABS-2014M1005885 |                                 | 26 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Contusion; Dizziness; Dysstasia; Headache; Hypoaesthesia; Injection Site Oedema; Migraine; Nausea; Skin Discolouration; Vomiting   | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk, Prn                        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Nov-2014  | 10447251                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2014M1004189 |                                 |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Effect Decreased  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             |                                 |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|---------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Nov-2014  | 10593118                        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1010539 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector            |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|  | Epipen Auto-Injector            |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Nov-2014  | 10593124                        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1010678 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector            |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Nov-2014  | 10609985                        | EXPEDITED (15-DAY) | Y                  | DE, HO          | IMP_08219_2014            |                      | 49 YR           | Female     | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Amputation; Gas Gangrene   | Promethazine (Promethazine)     |                    |                    | S               |                           | Until Not Continuing | 1 DAY           |            |                |
|  | Epipen (Epipen) (Not Specified) |                    |                    | S               | Subcutaneous              | Not Continuing       | 1 DAY           |            |                |
|  | Prednisone                      |                    |                    | C               | Intramuscular             | Not Continuing       | 2 YR            |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Dec-2014  | 10600287                        | EXPEDITED (15-DAY) |                    | LT              | JP-MYLANLABS-2014M1011076 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Haemorrhage; Injection Site Pain | Epipen                          |                    |                    | S               |                           | 0.15 Mg, Unk         |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|----------------------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 05-Dec-2014   | 10589050   | EXPEDITED (15-DAY) |                    | HO                         | US-ROCHE-1491028              |                      | 12 YR           | Male       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective;<br>Dyspnoea                               | Xolair<br>Epipen   |                    |                    | S<br>S                     | Subcutaneous<br>Unknown       |                      |                 |            |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Dec-2014   | 10637818   | EXPEDITED (15-DAY) |                    | HO, LT, OT                 | GB-MYLANLABS-<br>2014M1012604 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired<br>Device Used; No Adverse<br>Event | Epipen Auto-Injector 0.3 Mg<br>Loratadin<br>Montelukast<br>Prednisolone<br>Salbutamol<br>Symbicort |                    |                    | S<br>C<br>C<br>C<br>C<br>C | Intramuscular                 | .3 Mg, Unk           |                 | Mylan      |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Dec-2014   | 10637847   | EXPEDITED (15-DAY) |                    | OT                         | GB-MYLANLABS-<br>2014M1013085 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; No<br>Adverse Event                         | Epipen Auto-Injector 0.3 Mg  |                    |                    | S                          |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>            | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Dec-2014   | 10639346   | EXPEDITED (15-DAY) |                    | OT                         | US-MYLANLABS-<br>2014M1012200 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector   |                    |                    | S                          | Intramuscular                 | 0.3 Mg, Prn          |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 08-Dec-2014   | 10639350                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1012170 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury   | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Dec-2014   | 10646093                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1013597 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Injury | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Dec-2014   | 10647655                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1013514 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Device Used; Injection Site Haemorrhage     | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Dec-2014   | 10651524                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1013345 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Dec-2014   | 10656393                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1005959 |                      |                 | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Expired Product Administered; Vasoconstriction   | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Dec-2014  | 10657430                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1013952 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2014  | 10662168                 | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2014M1013966 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen Auto-Injector     |                    |                    | S               | Subcutaneous              | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Dec-2014  | 10568779                 | EXPEDITED (15-DAY) |                    | OT              | US-BAXTER-2014BAX065778   |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Angioedema; Blood Pressure Increased; Dark Circles Under Eyes; Diarrhoea; Dizziness; Food Allergy; Food Intolerance; Headache; Malaise; Muscle Spasms; Unevaluable Event; Yellow Skin | Gammagard Liquid         |                    |                    | S               | Subcutaneous              |                      |                 | Baxter     |                |
|  | Gammagard Liquid         |                    |                    | S               | Subcutaneous              |                      |                 | Baxter     |                |
|  | Epipen                   |                    |                    | S               | Unknown                   |                      |                 |            |                |
|  |                          |                    |                    |                 |                           |                      |                 |            |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 23-Dec-2014   | 10671419                           | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2014M1014946 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                      | Epipen                             |                    |                    | S               |                           | .3 Mg, Unk           |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Dec-2014   | 10677005                           | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2014M1014215 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                                    | Epipen Auto-Injector               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Dec-2014   | 10653471                           | EXPEDITED (15-DAY) |                    | DE              | US-MYLANLABS-2014M1013002 |                      |                 | Unknown    | MEX            |
| <u>Preferred Term</u>                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                      | Epipen Auto-Injector               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen Auto-Injector               |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Jan-2015   | 10691214                           | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2014M1015163 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Adverse Reaction;<br>Headache; Pyrexia;<br>Vomiting | Epipen Jr Adrenaline Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Jan-2015   | 10711201                           | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2014S1012373 |                      | 66 YR           | Female     | JPN            |
| <u>Preferred Term</u>                               | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|   |        |   |               |     |       |
|---|--------|---|---------------|-----|-------|
| Product Administered At Inappropriate Site; Product Quality Issue; Soft Tissue Foreign Body | Epipen | S | Intramuscular | Unk | Mylan |
|---|--------|---|---------------|-----|-------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 15-Jan-2015              | 10530371      | EXPEDITED (15-DAY) |                    | DE              | AU-MYLANLABS-2014M1007356 |                      |            | Unknown    | AUS            |

| <u>Preferred Term</u> | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Death                 | Epipen (Epinephrine) Auto Injector 0.3 Mg |              |            | S           | Unknown      | Unk                |                 | Mylan      |
|                       | Atorvastatin                              |              |            | C           |              | 20 Mg, Unk         |                 |            |
|                       | Clopidogrel                               |              |            | C           |              | 75 Mg, Unk         |                 |            |
|                       | Perindopril                               |              |            | C           |              | 2 Mg, Unk          |                 |            |
|                       | Lyrica                                    |              |            | C           |              | 300 Mg, Unk        |                 |            |
|                       | Lyrica                                    |              |            | C           |              | 150 Mg, Unk        |                 |            |
|                       | Pantoprazole                              |              |            | C           |              | 40 Mg, Unk         |                 |            |
|                       | Vesicare                                  |              |            | C           |              | 10 Mg, Unk         |                 |            |
|                       | Lantus                                    |              |            | C           |              | Unk                |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Jan-2015              | 10717673      | EXPEDITED (15-DAY) |                    | LT              | SE-MYLANLABS-2014M1000240 |                      |            | Unknown    | SWE            |

| <u>Preferred Term</u>                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; Drug Effect Incomplete | Epipen         |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 22-Jan-2015              | 10437499      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1002819 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Injection Site Injury; Syncope | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Mylan      |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 27-Jan-2015  | 10654430                            | EXPEDITED (15-DAY) |                    | HO, LT          | US-MYLANLABS-2014M1013987 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Wrong Technique In Product Usage Process | Epipen Auto-Injector<br>Epinephrine |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|  |                                     |                    |                    | S               | Intramuscular             | Unk                  |                 |            |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Feb-2015  | 10677280                            | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2014M1015066 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Unresponsive To Stimuli                                    | Epipen Auto-Injector                |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Feb-2015  | 10779188                            | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1002647 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector                |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Feb-2015  | 10779189                            | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2015M1003429 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective                           | Epipen Auto-Injector                |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Feb-2015  | 10785549                            | EXPEDITED (15-DAY) |                    | DE              | ZA-MYLANLABS-2015M1002736 |                      |                 | Unknown    | ZAF            |
| <u>Preferred Term</u>                                      | <u>Product</u>                      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                                    |                    |                    |                 |                           |                      |                 |            |                |
|--|------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Expired Device Used  | Epipen Auto-Injector               | S                  | Unk                | Mylan           |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Feb-2015  | 10785694                           | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1003021 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Jr. Auto-Injector           |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Feb-2015  | 10785777                           | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1002667 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injection Site Discolouration; Injection Site Hypoaesthesia; Pyrexia; Tremor | Epipen Auto-Injector               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10815359                           | EXPEDITED (15-DAY) |                    | LT              | AU-MYLANLABS-2015M1004751 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Needle Issue; Skin Wound; Therapeutic Response Delayed; Wound  | Epipen Jr Adrenaline Auto-Injector |                    |                    | S               |                           | 1 Df, Once           |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10816458                           | EXPEDITED (15-DAY) |                    | HO, LT          | US-MYLANLABS-2015M1003739 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|   |                          |                      |                    |                 |                           |                      |                 |            |                |  |
|---|--------------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|--|
| Device Failure; Drug Ineffective                          |                          | Epipen Auto-Injector |                    | S               | Intramuscular             |                      | 0.3 Mg, Prn     |            | Mylan          |  |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Feb-2015   | 10822279                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2014S1002701 |                      |                 | Female     | USA            |  |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure  | Epipen Jr. Auto-Injector |                      |                    | S               | Intramuscular             | .15 Mg,Prn           |                 | Mylan      |                |  |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Feb-2015   | 10822286                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2014S1000995 |                      |                 | Female     | USA            |  |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Accidental Exposure To Product                            | Epipen Auto-Injector     |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |  |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Feb-2015   | 10822293                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2014S1000535 |                      |                 | Female     | USA            |  |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure  | Epipen Auto-Injector     |                      |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |  |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Feb-2015   | 10822298                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2014S1003835 |                      |                 | Male       | USA            |  |
| <u>Preferred Term</u>                                     | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Accidental Exposure To Product; Injection Site Joint Pain | Epipen Auto-Injector     |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |  |
| <u>FDA Received Date</u>                                  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Feb-2015   | 10822303                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2014S1004164 |                      | 48 YR           | Female     | USA            |  |

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| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure                             | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | .3 Mg,Pn             |                 | Mylan      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                | 10822307                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1002227 |                      | 14 YR           | Female     | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Gait Disturbance; Injection Site Reaction; | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | .3 Mg,Pn             |                 | Mylan      |                |
| Musculoskeletal Stiffness                  | Epipen Auto-Injector     |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                | 10822311                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1004845 |                      | 58 YR           | Male       | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                             | Epipen Auto-Injector     |                  |                    | S               |                           | Unk Unk,Pn           |                 | Mylan      |                |
|  | Prednisone               |                  |                    | C               | Oral                      | 5 Mg,Qd              |                 |            |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                | 10822316                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1002692 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product             | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                | 10822320                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1007726 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product             | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015   | 10822324             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2014S1005403 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822329             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1007416 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822333             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1006643 |                      | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Increased; Dizziness; Heart Rate Increased | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | .3 Mg,Once           |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822339             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1008473 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Rate Increased  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk,Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822346             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1005962 |                      | 60 YR           | Male       | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Haemorrhage    | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822354             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1010969 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822361             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1010997 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; Unevaluable Event                  | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822367             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1011873 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                                | Epipen Auto-Injector |                  |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822376             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1006934 |                      | 33 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen Auto-Injector |                  |                    | S               |                           | Unk Unk              |                 | Mylan      |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015  | 10822381                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1017905 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                             | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822384                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1012853 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Haemorrhage | Epipen Auto-Injector     |                  |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822389                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1000935 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                             | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822391                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1002665 |                      | 8 YR            | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | .15 Mg,Pn            |                 | Mylan      |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822392                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1004460 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|  |                          |                  |                    |                 |                           |                      |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                      |                  |                    |                 |                           |                      |                 |            |                |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product                                | Epipen Auto-Injector |                  | S                  |                 |                           | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822394             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1002137 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Wrong Technique In Product Usage Process                      | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822395             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1002970 |                      | 61 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Pain                           | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | .3 Mg,Prn            |                 |            | Mylan          |
|   | Claritin /00917501/  |                  |                    | C               |                           | Unk                  |                 |            |                |
|   | Potassium            |                  |                    | C               |                           | Unk                  |                 |            |                |
|   | Ceftin /00454603/    |                  |                    | C               |                           | 250 Mg,Unk           |                 |            |                |
|   | Blood Pressure Pill  |                  |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822398             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1003884 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Gait Disturbance; Injection Site Bruising; Muscle Haemorrhage | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | .3 Mg,Prn            |                 |            | Mylan          |
|   | Benefix              |                  |                    | C               |                           | Unk Unk,3xw          |                 |            |                |
|   | Benadryl             |                  |                    | C               |                           | Unk Unk,3xw          |                 |            |                |
|   | Heparin Lock Flush   |                  |                    | C               |                           | Unk Unk,3xw          |                 |            |                |
|   | Finasteride          |                  |                    | C               |                           | Unk                  |                 |            |                |
|   | Clonazepam           |                  |                    | C               |                           | Unk                  |                 |            |                |
|   | Mirtazapine          |                  |                    | C               |                           | Unk                  |                 |            |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015   | 10822400             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1000444 |                      | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Burning Sensation; Gait Disturbance   | Epipen Auto-Injector |                  |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822403             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1002851 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Injury; Injection Site Pain    | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822405             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1005397 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Intentional Product Misuse; Unevaluable Event | Epipen Auto-Injector |                  |                    | S               |                           | .6 Mg,Once           |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822406             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1003833 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Unevaluable Event                             | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015   | 10822407             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1006081 |                      | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain   | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |
|   | Benadryl             |                  |                    | C               | Oral                      | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822408             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1000457 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered                          | Epipen Auto-Injector |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822409             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1004461 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Swelling | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822410             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1004523 |                      | 6 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Pain                          | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015  | 10822411             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1001328 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Swelling; Peripheral Swelling | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822412             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1007601 |                      | 59 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Defective   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822413             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1003241 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822414             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1004159 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Drug Ineffective                                      | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | .3 Mg,Prn            |                 | Mylan      |                |
|  | Benefix              |                    |                    | C               |                           | Unk Unk,3xw          |                 |            |                |
|  | Benadryl             |                    |                    | C               |                           | Unk Unk,3xw          |                 |            |                |
|  | Heparin Lock Flush   |                    |                    | C               |                           | Unk Unk,3xw          |                 |            |                |
|  | Finasteride          |                    |                    | C               |                           | Unk                  |                 |            |                |

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|             |   |     |
|-------------|---|-----|
| Clonazepam  | C | Unk |
| Mirtazapine | C | Unk |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Feb-2015                       | 10822415               | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1002705     |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure                 | Epipen Auto-Injector    |                       |                     | S                    | Intramuscular         | .3 Mg,Prn                   |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Feb-2015                       | 10822416               | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014M1000520     |                               |                     | Male                | USA                     |

| <a href="#">Preferred Term</a>                                | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Accidental Exposure To Product By Child; Heart Rate Increased | Epipen Auto-Injector    |                       |                     | S                    |                       |                             |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Feb-2015                       | 10822417               | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2014S1004303     |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>  | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|--------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Accidental Exposure To Product | Epipen Jr. Auto-Injector |                       |                     | S                    |                       | Unk                         |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Feb-2015                       | 10822419               | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2013S1029037     |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure                 | Epipen Auto-Injector    |                       |                     | S                    | Intramuscular         | Unk                         |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 18-Feb-2015                       | 10822420               | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1002853     |                               |                     | Male                | USA                     |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product                            | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822421             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1017338 |                      | 57 YR           | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Paraesthesia; Tremor                                      | Epipen Auto-Injector |                    |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
|   | Benadryl             |                    |                    | S               |                           | Unk Unk,Once         |                 |            |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822422             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1005783 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Ventricular Extrasystoles | Epipen Auto-Injector |                    |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822423             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1004414 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Jittery; Somnolence                               | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Benadryl             |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822425             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1002700 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Injection Site Scar;                 | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

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Product Administered At  
Inappropriate Site

| <u>FDA Received Date</u>                                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015   | 10822427                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1005351 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | .15 Mg,Prn           |                 | Mylan      |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822428                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1001821 |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Wrong Technique In<br>Product Usage Process                 | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |
|   | Risperdal                |                  |                    | C               |                           | Unk                  |                 |            |                |
|   | Synthroid                |                  |                    | C               | Oral                      | Unk                  |                 |            |                |
|   | Cholesterol Medication   |                  |                    | C               | Oral                      | Unk                  |                 |            |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822429                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1000831 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product                           | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822430                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1000996 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injection Site<br>Oedema | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |



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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822432      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1007732 |                      |            | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product | Epipen Auto-Injector |              |            | S           |              | Unk Unk,Once       |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822433      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1007562 |                      | 70 YR      | Male       | USA            |

| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>                          | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------------|--------------|------------|-------------|---------------------------------------|--------------------|-----------------|------------|
| Fatigue; Injection Site Pain; Nervousness | Epipen Auto-Injector |              |            | S           | Intramuscular                         | .3 Mg,Prn          |                 | Mylan      |
|   | Solu-Medrol          |              |            | S           | Intravenous (not otherwise specified) | Unk                |                 |            |
|   | Prednisone           |              |            | S           | Oral                                  | Unk                |                 |            |
|   | Lantus               |              |            | C           | Subcutaneous                          | Unk                |                 |            |
|   | Novolog              |              |            | C           | Subcutaneous                          | Unk                |                 |            |
|   | Keppra               |              |            | C           | Oral                                  | Unk                |                 |            |
|   | Metformin            |              |            | C           | Oral                                  | Unk                |                 |            |
|   | Lipitor              |              |            | C           | Oral                                  | Unk                |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822434      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1000248 |                      |            | Female     | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product | Epipen Auto-Injector |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822435      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1000265 |                      |            | Male       | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822436                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1016859     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Administration Error; No Adverse Event                                  | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822437                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1007539     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Exposure During Pregnancy; Unevaluable Event | Epipen Auto-Injector    |                           |                             | S                        |                               | .3 Mg,Prn                     |                          | Mylan               |                         |
|  | Epipen Auto-Injector    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
|  | Epipen Auto-Injector    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
|  | Benadryl                |                           |                             | C                        |                               | Unk                           |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822438                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1003438     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Administration Error  | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk Unk,Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822440                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1008559     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pain   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015   | 10822441                               | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1004863 |                      | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Expired Product Administered | Epipen Auto-Injector<br>Tetanus Vaccin |                    |                    | S<br>C          |                           | Unk Unk, Once<br>Unk |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822445                               | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1008512 |                      | 13 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia; Swelling               | Epipen Auto-Injector                   |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822446                               | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1005825 |                      | 10 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child                               | Epipen Jr. Auto-Injector               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822447                               | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1000743 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Discolouration         | Epipen Auto-Injector                   |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822451                               | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1006028 |                      |                 | Female     | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822453                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014M1008413     |                               | 23 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Incorrect Dose Administered; Wrong Technique In Product Usage Process                          | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk, Once                     |                          | Mylan               |                         |
|  | Epipen Auto-Injector    |                           |                             | S                        |                               |                               | Mylan                    |                     |                         |
|  | Epipen Auto-Injector    |                           |                             | S                        |                               |                               | Mylan                    |                     |                         |
|  | Zyrtec                  |                           |                             | C                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822454                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1006646     |                               | 49 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pain; Nervousness | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | .15 Mg,Once                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822457                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1009436     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Nervousness  | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015  | 10822459                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1005821     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|   |                          |                  |                    |                 |                           |                      |                 |            |                |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Circumstance Or Information Capable Of Leading To Medication Error; Injection Site Pain | Epipen Auto-Injector     | S                |                    |                 |                           | .3 Mg,Prn            |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822460                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1011214 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | .3 Mg,Once           |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822461                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1009438 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822462                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1010495 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Incomplete; Swelling Face   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822465                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1009460 |                      | 3 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | .15 Mg,Prn           |                 |            | Mylan          |
|   | Epipen Jr. Auto-Injector |                  |                    | S               |                           |                      |                 |            | Mylan          |
|   | Epipen Jr. Auto-Injector |                  |                    | S               |                           |                      |                 |            | Mylan          |
|   | Benadryl                 |                  |                    | C               |                           | Unk                  |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015  | 10822466                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1000299 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury  | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | .15 Mg,Pn            |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822468                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1007906 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain  | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822469                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1014190 |                      | 44 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Device Used; Injection Site Pain | Epipen Auto-Injector     |                  |                    | S               | Subcutaneous              | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822471                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1004508 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822472                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1012232 |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|  |                          |                  |                    |                 |                           |                      |                 |            |                |

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|   |                          |                          |                    |                 |                           |                    |                      |                 |            |                |
|---|--------------------------|--------------------------|--------------------|-----------------|---------------------------|--------------------|----------------------|-----------------|------------|----------------|
| Device Failure  |                          | Epipen Jr. Auto-Injector |                    | S               | Intramuscular             |                    | .15 Mg,Prn           |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822473                 | NON-EXPEDITED            |                    |                 | US-MYLANLABS-2014S1009823 |                    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen Auto-Injector     |                          |                    | S               |                           | Unk                |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822475                 | NON-EXPEDITED            |                    |                 | US-MYLANLABS-2014S1010835 |                    |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Hypoaesthesia; Peripheral Coldness; Poor Peripheral Circulation | Epipen Auto-Injector     |                          |                    | S               |                           | Unk                |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822476                 | NON-EXPEDITED            |                    |                 | US-MYLANLABS-2014S1008827 |                    |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                          |                    | S               | Intramuscular             | .3 Mg,Prn          |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822477                 | NON-EXPEDITED            |                    |                 | US-MYLANLABS-2014S1011600 |                    |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Oedema   | Epipen Jr. Auto-Injector |                          |                    | S               |                           | Unk Unk,Once       |                      |                 | Mylan      |                |
|   | Qvar                     |                          |                    | C               |                           | Unk                |                      |                 |            |                |

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| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015                    | 10822478             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1011240 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Nausea                         | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |
|                                | Nexium               |                  |                    | C               |                           | Unk                  |                 |            |                |
|                                | Levothyroxine        |                  |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                    | 10822480             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1014785 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising        | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                    | 10822481             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1015950 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product | Epipen Auto-Injector |                  |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                    | 10822482             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1010844 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product | Epipen Auto-Injector |                  |                    | S               |                           | .3 Mg,Once           |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                    | 10822485             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1003732 |                      |                 | Female     | USA            |



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| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Malaise  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822486                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1002288 |                      | 4 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Injury; Palpitations; Somnolence | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822487                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1012951 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822488                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1009848 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Haemorrhage   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822489                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1015098 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Glossodynia; Tremor  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015  | 10822491                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1015227 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | .15 Mg,Once          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822492                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1013486 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Muscle Twitching             | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822493                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1009941 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Rash Generalised   | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | .15 Mg,Prn           |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822499                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1016333 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                               | Epipen Auto-Injector     |                    |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822501                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2014M1003397 |                      | 31 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |   |               |     |       |
|--|----------------------|---|---------------|-----|-------|
| Anaphylactic Reaction;<br>Drug Ineffective | Epipen Auto-Injector | S | Intramuscular | Unk | Mylan |
|  | Epipen Auto-Injector | S |               |     | Mylan |
|  | Motrin               | C |               | Unk |       |
|  | Benadryl /00000402/  | C |               |     |       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822502      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1015472 |                      |            | Male       | USA            |

| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product | Epipen Auto-Injector |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822504      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1016351 |                      | 34 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Injection Site Bruising; Injection Site Pain; Injection Site Swelling | Epipen Jr. Auto-Injector |              |            | S           |              | .15 Mg,Once        |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822507      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1003906 |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>                                 | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Injection Site Injury | Epipen Jr. Auto-Injector |              |            | S           |              | Unk Unk, Once      |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 18-Feb-2015              | 10822511      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1001192 |                      | 21 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|   |                          |                    |                    |                 |                           |                      |                 |            |                |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector     | S                  | Intramuscular      | 0.3 Mg, Prn     |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822512                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1014127 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Expired Product Administered | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822514                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1016004 |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child                               | Epipen Auto-Injector     |                    |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822518                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1006702 |                      | 74 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822521                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1016545 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Flutter   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822522                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1009056 |                      |                 | Female     | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Haemorrhage; Injury Associated With Device | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822524             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1005029 |                      | 63 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822525             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1009050 |                      | 47 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Dyspnoea; Wheezing  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822526             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1011119 |                      | 48 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Swelling Face   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | .3 Mg,Prn            |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           |                      | Mylan           |            |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           |                      | Mylan           |            |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           |                      | Mylan           |            |                |
|   | Lactulose            |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Aspirin              |                    |                    | C               |                           | 81 Mg,Unk            |                 |            |                |
|   | Hydrocodone          |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Amlodipine           |                    |                    | C               |                           | 10 Mg,Unk            |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015  | 10822527             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1003236 |                      | 76 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased;<br>Injection Site Pain;<br>Swollen Tongue | Epipen Auto-Injector |                  |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822529             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1015507 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction   | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822532             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1014639 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Prescribing Error   | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822533             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1013773 |                      | 41 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Palpitations   | Epipen Auto-Injector |                  |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822534             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1006373 |                      | 28 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                          |                      |                    |                 |                           |                      |                 |            |                |
|--|--------------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Drug Ineffective; Rash           |                          | Epipen Auto-Injector |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                      | 10822538                 | EXPEDITED (15-DAY)   |                    | OT              | US-MYLANLABS-2014M1003847 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Anxiety | Epipen Jr. Auto-Injector |                      |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                      | 10822539                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2014S1016858 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; No Adverse Event      | Epipen Auto-Injector     |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                      | 10822543                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2014S1016856 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; No Adverse Event      | Epipen Auto-Injector     |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015                                      | 10822545                 | EXPEDITED (15-DAY)   |                    | OT              | US-MYLANLABS-2014M1006332 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Drug Ineffective          | Epipen Auto-Injector     |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Klonopin                 |                      |                    | C               |                           | Unk                  |                 |            |                |
|  | Vistaril /00058402/      |                      |                    | C               |                           | Unk                  |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015  | 10822546                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1000094 |                      | 43 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased;<br>Expired Product<br>Administered; Intentional<br>Product Misuse | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Epipen Jr. Auto-Injector |                  |                    | S               |                           |                      |                 | Mylan      |                |
|  | Epipen Jr. Auto-Injector |                  |                    | S               |                           |                      |                 | Mylan      |                |
|  | Prednisone               |                  |                    | C               |                           |                      |                 |            |                |
|  | Steroid Antibacterials   |                  |                    | C               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822548                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1015600 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Expired Product<br>Administered                       | Epipen Auto-Injector     |                  |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822553                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1014523 |                      | 10 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product By Child; No<br>Adverse Event                          | Epipen Auto-Injector     |                  |                    | S               |                           | .3 Mg,Once           |                 | Mylan      |                |
|  | Albuterol                |                  |                    | C               |                           | Unk                  |                 |            |                |
|  | Zyrtec                   |                  |                    | C               |                           | Unk                  |                 |            |                |
|  | Epipen                   |                  |                    | C               |                           | Unk                  |                 |            |                |
|  | Flonase /00972202/       |                  |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822554                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1003006 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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|   |                          |                           |                             |                          |                               |                       |                               |                          |                     |                         |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Heart Rate Increased                    | Epipen Auto-Injector     |                           | S                           |                          | Intramuscular                 |                       | 0.3 MI, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015                             | 10822556                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1015690     |                       |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product          | Epipen Auto-Injector     |                           |                             |                          | S                             |                       | Unk Unk,Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015                             | 10822558                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014M1001841     |                       |                               | 5 YR                     | Unknown             | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child | Epipen Jr. Auto-Injector |                           |                             |                          | S                             |                       | 0.15 Mg, Total                |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015                             | 10822559                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014M1008736     |                       |                               | 19 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered            | Epipen Auto-Injector     |                           |                             |                          | S                             | Intramuscular         | 0.3 Mg, Once                  |                          | Mylan               |                         |
|   | Oral Contraceptive Nos   |                           |                             |                          | C                             |                       | Unk                           |                          |                     |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015                             | 10822560                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1017005     |                       |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Swelling Face                           | Epipen Auto-Injector     |                           |                             |                          | S                             |                       | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Feb-2015                             | 10822561                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014S1015857     |                       |                               |                          | Female              | USA                     |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Expired Product Administered                              | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822563             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1009113 |                      | 72 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822568             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1000607 |                      | 29 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pain; Tremor | Epipen Auto-Injector |                  |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822569             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1014214 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness; Heart Rate Irregular; Vomiting   | Epipen Auto-Injector |                  |                    | S               |                           | Unk Unk,Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822571             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1013972 |                      | 42 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain   | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015   | 10822572                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014S1015696 |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk Unk,Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822575                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1009166 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error; Incorrect Dose Administered; Oxygen Saturation Decreased; Upper Respiratory Tract Inflammation | Epipen                   |                  |                    | S               |                           | Unk Unk, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822576                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1000384 |                      | 14 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen Auto-Injector     |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822578                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1004239 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Pain In Extremity; Skin Discolouration                      | Epipen Auto-Injector     |                  |                    | S               |                           | 0.3 Mg, Prn          |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Feb-2015  | 10822586                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1010983 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                                   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822588                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014S1016902 |                      | 4 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child                          | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822592                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1005945 |                      | 22 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                                   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822599                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1014414 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Erythema | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015  | 10822601                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1013773 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|   |                             |                    |                    |                 |                           |                           |                 |            |                |
|---|-----------------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector        | S                  | Intramuscular      | 0.3 Mg, Prn     |                           |                           |                 | Mylan      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822632                    | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1013513 |                           | 36 YR           | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector        | S                  | Intramuscular      | 0.3 Mg, Prn     |                           |                           |                 | Mylan      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10822638                    | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2014M1009624 |                           |                 | Male       | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue                              | Epipen Auto-Injector        | S                  | Intramuscular      | 0.3 Mg, Prn     |                           |                           |                 | Mylan      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Feb-2015   | 10855539                    | DIRECT             |                    | OT              |                           |                           | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Burning Sensation; Drug Ineffective; Feeling Hot; Malaise | Epipen                      | S                  |                    |                 |                           | Given Into/Under The Skin |                 | Mylan      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Feb-2015   | 10857898                    | EXPEDITED (15-DAY) |                    | DE, OT          | GB-MYLANLABS-2015M1004820 |                           |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                     | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Status Asthmaticus                      | Epipen Auto-Injector 0.3 Mg | S                  |                    |                 |                           |                           |                 | Mylan      |                |
| <u>FDA Received Date</u>                                  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Feb-2015   | 10858241                    | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2015M1004149 |                           |                 | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective   | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Feb-2015  | 10633457                    | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2014M1012537 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered   | Epipen Auto-Injector        |                    |                    | S               | Unknown                   | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Feb-2015  | 10872033                    | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2015M1006181 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen                      |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Feb-2015  | 10611841                    | EXPEDITED (15-DAY) |                    | HO, OT          | GB-MYLANLABS-2014M1011745 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock; Drug Ineffective; Generalised Erythema; Hypotension; Pruritus; Pyrexia; Tremor | Epipen Auto-Injector 0.3 Mg |                    |                    | S               |                           | 1 Df, 5xd            |                 | Mylan      |                |
|  | Epipen Auto-Injector 0.3 Mg |                    |                    | S               |                           |                      |                 | Mylan      |                |
|  | Amoxicillin                 |                    |                    | S               |                           | Unk                  |                 |            |                |
|  | Codeine Linctus             |                    |                    | S               |                           | Unk                  |                 |            |                |
|  | Diffiam                     |                    |                    | C               |                           |                      |                 |            |                |
|  | Candesartan                 |                    |                    | C               |                           |                      |                 |            |                |
|  | Cyanocobalamin              |                    |                    | C               |                           |                      |                 |            |                |
|  | Ezetimibe                   |                    |                    | C               |                           |                      |                 |            |                |
|  | Insulatard /00646002/       |                    |                    | C               |                           |                      |                 |            |                |
|  | Istin                       |                    |                    | C               |                           |                      |                 |            |                |
|  | Loperamide                  |                    |                    | C               |                           |                      |                 |            |                |
|  | Peptac /00550802/           |                    |                    | C               |                           |                      |                 |            |                |
|  | Paracetamol                 |                    |                    | C               |                           |                      |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                     |   |     |
|---------------------|---|-----|
| Atorvastatin        | C | Unk |
| Gaviscon /00237601/ | C |     |
| Insulin             | C |     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 27-Feb-2015              | 10874610      | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2015M1005832 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>            | <u>Product</u>              | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|-----------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; No Adverse Event | Epipen Auto-Injector 0.3 Mg |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 02-Mar-2015              | 10877881      | EXPEDITED (15-DAY) |                    | OT              | FI-MYLANLABS-2015M1006066 |                      |            | Unknown    | FIN            |

| <u>Preferred Term</u>            | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; No Adverse Event | Epipen Jr      |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 04-Mar-2015              | 10888284      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1005401 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                     | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; Injection Site Laceration | Epipen Jr. Auto-Injector |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 08-Mar-2015              | 10896040      | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2015M1002228 |                      |            | Unknown    | JPN            |

| <u>Preferred Term</u>                         | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|---------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Iliotibial Band Syndrome; Injection Site Pain | Epipen              |              |            | S           | Intramuscular | 0.3 Mg, Unk        |                 | Mylan      |
|   | Epipen              |              |            | S           |               |                    |                 | Mylan      |
|   | Epipen              |              |            | S           |               |                    |                 | Mylan      |
|   | Clarityn /00917501/ |              |            | S           | Oral          | 10 Mg, Qd          |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clarityn /00917501/

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------------|----------------------|------------|------------|----------------|
| 11-Mar-2015              | 10903117      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-AUROBINDO-AUR-<br>APL-2015-01891 |                      | 69 YR      | Female     | GBR            |

| <u>Preferred Term</u>  | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anaphylactic Shock; Drug Ineffective; Generalised Erythema; Heart Rate Irregular; Hypotension; Pruritus; Pyrexia; Tremor | Amoxicillin           |              |            | S           | Unknown      | Unk                |                 | Aurobindo  |
|  | Codeine Linctus       |              |            | S           | Unknown      | Unk                |                 |            |
|  | Epipen                |              |            | S           | Unknown      |                    |                 |            |
|  | Atorvastatin          |              |            | C           | Unknown      | Unk                |                 |            |
|  | Candesartan           |              |            | C           | Unknown      | Unk                |                 |            |
|  | Cyanocobalamin        |              |            | C           | Unknown      | Unk                |                 |            |
|  | Diffiam               |              |            | C           | Unknown      | Unk                |                 |            |
|  | Ezetimibe             |              |            | C           | Unknown      | Unk                |                 |            |
|  | Gaviscon /00237601/   |              |            | C           | Unknown      | Unk                |                 |            |
|  | Insulatard /00646002/ |              |            | C           | Unknown      | Unk                |                 |            |
|  | Insulin               |              |            | C           | Unknown      | Unk                |                 |            |
|  | Istin                 |              |            | C           | Unknown      | Unk                |                 |            |
|  | Loperamide            |              |            | C           | Unknown      | Unk                |                 |            |
|  | Paracetamol           |              |            | C           | Unknown      | Unk                |                 |            |
|  | Acidex                |              |            | C           | Unknown      | Unk                |                 |            |
|  | Peptac /01521901/     |              |            | C           | Unknown      | Unk                |                 |            |
|  | B12 /00056201/        |              |            | C           | Unknown      | Unk, Monthly       |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 11-Mar-2015              | 10903352      | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2014GB169469     |                      | 69 YR      | Female     | GBR            |

| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|-------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Anaphylactic Shock; Drug Ineffective; Generalised Erythema; Hypotension; | Codeine Phosphate |              |            | S           | Unknown      |                    |                 |            |
|  | Amoxicillin       |              |            | S           | Unknown      |                    |                 | Novartis   |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                     |   |         |           |
|---------------------------|---------------------|---|---------|-----------|
| Pruritus; Pyrexia; Tremor | Epipen              | S | Unknown | 1 Df, 5qd |
|                           | Diffiam             | C | Unknown |           |
|                           | Candesartan         | C | Unknown |           |
|                           | Cyanocobalamin      | C | Unknown |           |
|                           | Ezetimibe           | C | Unknown |           |
|                           | Insulatard          | C | Unknown |           |
|                           | Istin               | C | Unknown |           |
|                           | Acidex              | C | Unknown |           |
|                           | Loperamide          | C | Unknown |           |
|                           | Paracetamol         | C | Unknown |           |
|                           | Peptac              | C | Unknown |           |
|                           | Atorvastatin        | C | Unknown |           |
|                           | Gaviscon /01279101/ | C | Unknown |           |
|                           | Insulin             | C | Unknown |           |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>    | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------|----------------------|------------|------------|----------------|
| 16-Mar-2015              | 10915747      | EXPEDITED (15-DAY) |                    | HO, OT          | GB-RANBAXY-2015RR-94175 |                      |            | Unknown    | GBR            |

| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |
|--|-----------------|--------------|------------|-------------|--------------|--|-----------------|------------|
| Anaphylactic Shock; Drug Ineffective; Generalised Erythema; Hypotension; Pruritus; Pyrexia; Tremor | Amoxicillin     |              |            | S           | Unknown      | Unk  |                 | Ranbaxy    |
|  | Codeine Linctus |              |            | S           | Unknown      | Unk  |                 |            |
|  | Epipen          |              |            | S           | Unknown      | 1 Df 5 Times A Day, Solution For Injection In Pre-Filled Pen |                 |            |
|  | Atorvastatin    |              |            | C           | Unknown      | Unk  |                 |            |
|  | Candesartan     |              |            | C           | Unknown      | Unk  |                 |            |
|  | Cyanocobalamin  |              |            | C           | Unknown      | Unk  |                 |            |
|  | Diffiam         |              |            | C           | Unknown      | Unk  |                 |            |
|  | Ezetimibe       |              |            | C           | Unknown      | Unk  |                 |            |
|  | Gaviscon        |              |            | C           | Unknown      | Unk  |                 |            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|             |   |         |     |
|-------------|---|---------|-----|
| Insulatard  | C | Unknown | Unk |
| Insulin     | C | Unknown | Unk |
| Istin       | C | Unknown | Unk |
| Loperamide  | C | Unknown | Unk |
| Paracetamol | C | Unknown | Unk |
| Acidex      | C | Unknown | Unk |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 31-Mar-2015              | 10969877      | EXPEDITED (15-DAY) |                    | HO              | AU-MYLANLABS-2015M1008881 |                      |            | Unknown    | AUS            |

| <u>Preferred Term</u>                    | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Wrong Technique In Product Usage Process | Epipen Jr Adrenaline Auto-Injector |              |            | S           | Unknown      |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Apr-2015              | 10973741      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1009652 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure        | Epipen Auto-Injector |              |            | S           | Intramuscular | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Apr-2015              | 9559979       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2013275228 |                      | 57 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|-----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity; Injection Site Swelling; Pyrexia; Rash | Zoloft          |              |            | S           |              | Unk                |                 | Pfizer     |
|   | Epipen          |              |            | S           |              | Unk                |                 | Pfizer     |
|   | Zofran          |              |            | S           |              | Unk                |                 |            |
|   | Vitamin B       |              |            | S           |              | Unk                |                 |            |
|   | Tetanus Vaccine |              |            | S           |              | Unk                |                 |            |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 23-Apr-2015  | 11058469                    | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2015M1013028 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Device Used  | Epipen Auto-Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-May-2015  | 11032954                    | EXPEDITED (15-DAY) |                    | LT              | NZ-MYLANLABS-2015M1010846 |                      |                 | Unknown    | NZL            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                       | Epipen                      |                    |                    | S               |                           | 300 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-May-2015  | 11051528                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1011755 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                       | Epipen Auto-Injector        |                    |                    | S               |                           | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-May-2015  | 11073602                    | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2015M1013795 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury; Injury Associated With Device | Epipen                      |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-May-2015  | 11101519                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1011845 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|   |                      |                    |                    |                 |                           |                      |                 |            |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Myocardial Infarction   | Epipen Auto-Injector |                    | S                  |                 |                           | 0.3 Mg, Unk          |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-May-2015   | 10822497             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2014M1001426 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Rate Increased; Injection Site Coldness; Injection Site Discolouration; Injection Site Hypoaesthesia; Injection Site Injury; Pain; Paraesthesia; Vasoconstriction; Wrong Technique In Product Usage Process | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-May-2015   | 11120250             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1015040 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury; Wrong Technique In Product Usage Process   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-May-2015   | 11123154             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1015271 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-May-2015   | 11130016             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1013673 |                      |                 | Unknown    | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product; Device Failure; Drug Ineffective; Injection Site Bruising; Injection Site Pain; Injection Site Swelling | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|   | Epipen Auto-Injector     |                           |                             | S                        |                               | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-May-2015   | 11130029                 | EXPEDITED (15-DAY)        |                             | LT                       | SE-MYLANLABS-2015M1016646     |                               |                          | Unknown             | SWE                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Ineffective; Needle Issue; Pain  | Epipen                   |                           |                             | S                        | Intramuscular                 | 150 Mg, Unk                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-May-2015   | 11137612                 | EXPEDITED (15-DAY)        |                             | OT                       | CA-MYLANLABS-2015M1016748     |                               |                          | Unknown             | CAN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen                   |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-May-2015   | 11137625                 | EXPEDITED (15-DAY)        |                             | LT                       | US-MYLANLABS-2015M1016267     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-May-2015   | 11142819                 | EXPEDITED (15-DAY)        |                             | LT                       | CA-MYLANLABS-2015M1016279     |                               |                          | Unknown             | CAN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|   |  |                    |                    |                 |                           |                      |                 |            |                |
|---|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective  |  | Epipen             |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-May-2015   | 11103005   | EXPEDITED (15-DAY) |                    | DE, OT          | AU-MYLANLABS-2015M1015477 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered                      | Epipen (Epinephrine) Auto Injector 0.3 Mg Tramadol Hydrochloride |                    |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
|   |  |                    |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Jun-2015   | 11156928   | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2015M1017827 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen   |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Jun-2015   | 10997498   | EXPEDITED (15-DAY) |                    | DE              | CA-MYLANLABS-2015M1008934 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; Food Allergy                          | Epipen   |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Jun-2015   | 11160221   | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1017105 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered; Injection Site Injury | Epipen Auto-Injector   |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Jun-2015   | 10696066                 | EXPEDITED (15-DAY)        |                             | OT                       | CA-MYLANLABS-2014M1016138     |                               |                          | Unknown             | CAN                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure;<br>Hypersensitivity; Injection<br>Site Injury; Scar | Epipen Jr<br>Epinephrine |                           |                             | S<br>S                   |                               | Unk, Once<br>Unk, 2x          |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 08-Jun-2015   | 11173302                 | EXPEDITED (15-DAY)        |                             | HO, LT                   | US-MYLANLABS-2015M1017568     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Jun-2015   | 11175922                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2015M1017727     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Injury   | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jun-2015   | 11178908                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2015M1017734     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Jun-2015   | 11178911                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2015M1017970     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                      | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System

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### Detailed Report

|  |   |                                 |               |  |       |
|--|---|---------------------------------|---------------|--|-------|
| Accidental Exposure To Product; Crying; Injection Site Discolouration; Injection Site Hypoaesthesia; Skeletal Injury; Skin Exfoliation | Epipen Auto-Injector<br>Zoloft<br>Plavix<br>Acebutolol<br>Metformin<br>Prilosec /00661201/<br>Singulair | S<br>C<br>C<br>C<br>C<br>C<br>C | Intramuscular | 0.3 Mg, Once<br>Unk<br>Unk<br>Unk<br>Unk<br>Unk<br>Unk | Mylan |
|--|---|---------------------------------|---------------|--|-------|

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 15-Jun-2015              | 11190060       | EXPEDITED (15-DAY) |                    | DE              | CA-MYLANLABS-2015M1019762 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen         |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Jun-2015              | 11193391             | EXPEDITED (15-DAY) |                    | HO              | ZA-MYLANLABS-2015M1018632 |                      |                 | Unknown    | ZAF            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |

| <u>FDA Received Date</u>                                    | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 18-Jun-2015   | 11199624       | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-K201000799 |                      |                 | Male       | CAN            |
| <u>Preferred Term</u>                                       | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Nerve Damage | Epipen Jr      |                    |                    | S               |                          | 0.15 Mg, Single      |                 | Pfizer     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 22-Jun-2015              | 11206332       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1019192 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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|   |                      |                    |                    |   |                           |                      |                 |            |                |
|---|----------------------|--------------------|--------------------|---|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector | S                  | Intramuscular      | 0.3 Mg, Once  | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2015   | 11206335             | EXPEDITED (15-DAY) | HO                 |   | US-MYLANLABS-2015M1019327 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>   | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector | S                  | Intramuscular      | 0.3 Mg, Once  | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jun-2015   | 11211897             | EXPEDITED (15-DAY) | HO                 |   | JP-MYLANLABS-2015M1020123 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>   | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Stress Cardiomyopathy   | Epipen               | S                  | Intradermal        | Approx 0.17mg Of 1:200 000 Epinephrine; Administered With 35ml Of Local Anaesthetic | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Jun-2015   | 11218707             | EXPEDITED (15-DAY) | OT                 |   | US-MYLANLABS-2015M1019926 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>   | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Decreased; Expired Product Administered; Injection Site Discolouration; Injection Site Pallor; Loss Of Consciousness | Epipen Auto-Injector | S                  | Once               | Mylan   |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2015   | 11228836             | EXPEDITED (15-DAY) | OT                 |   | US-MYLANLABS-2015M1020515 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>   | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |   |                    |                    |                 |                           |                      |                 |            |                |
|--|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure   | Epipen Auto-Injector                      | S                  | Intramuscular      | 0.3 Mg, Prn     |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2015  | 11229517                                  | EXPEDITED (15-DAY) |                    | LT              | DE-MYLANLABS-2015M1006342 |                      |                 | Unknown    | DEU            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue; Therapeutic Response Delayed   | Epipen Jr                                 |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2015  | 11232245                                  | DIRECT             |                    |                 |                           |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Dispensing Error  | Epipen Jr. Auto-Injector<br>Epipen        |                    |                    | S<br>S          |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jul-2015  | 10742537                                  | EXPEDITED (15-DAY) |                    | DE, OT          | AU-MYLANLABS-2015M1000819 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Drug Ineffective; Expired Product Administered  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Jul-2015  | 11243345                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1021574 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Device Failure; Injection Site Discolouration; Injection Site Injury; Injection Site | Epipen Auto-Injector                      |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |

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Pallor

| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Jul-2015   | 11247520                | EXPEDITED (15-DAY)        |                             | OT                       | DK-MYLANLABS-2015M1022018     |                               |                          | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Ineffective  | Epipen 0,3 Mg/Dosis     |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jul-2015   | 11267383                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2015M1022275     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Dyspnoea  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Jul-2015   | 11270952                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2015M1022321     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Dyschromatopsia; Euphoric Mood; Facial Paralysis; Gait Deviation; Hyperacusis; Mydriasis; Photophobia; Tremor | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk, Once                     |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Jul-2015   | 11231911                | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2015M1021747     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Laceration  | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Qd                   |                          | Mylan               |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
|---|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|----------------------|----------------|
| 21-Jul-2015   | 11289903                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1023125 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Device Failure; Drug Ineffective  | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan                |                |
|   | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan                |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 21-Jul-2015   | 11291958                    | DIRECT             | Y                  | OT              |                           |                      | 71 YR           | Male                 | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Drug Administration Error; Injury Associated With Device                                  | Epi-Pen Autoinjector 0.3 Mg |                    |                    | S               |                           |                      |                 | Lineage Therapeutics |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 27-Jul-2015   | 11314899                    | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2015M1024414 |                      |                 | Unknown              | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Device Failure; Dyspnoea; Heart Rate Irregular  | Epipen                      |                    |                    | S               |                           | Unk                  |                 | Mylan                |                |
| <u>FDA Received Date</u>  | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>           | <u>Country</u> |
| 29-Jul-2015   | 11319570                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1025109 |                      |                 | Unknown              | USA            |
| <u>Preferred Term</u>   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>           |                |
| Accidental Exposure To Product; Device Failure; Drug Ineffective; Injection Site Erythema | Epipen Auto-Injector        |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan                |                |
|   | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan                |                |

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| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|---|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 30-Jul-2015  | 11323646                                  | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2015M1025770     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered; Product Use Issue                                    | Epipen                                    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Daily                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Jul-2015  | 11323668                                  | EXPEDITED (15-DAY)        |                             | CA, OT                   | AU-MYLANLABS-2015M1025765     |                               |                          | Unknown             | AUS                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foetal Exposure During Pregnancy; Meningitis Neonatal                              | Epipen (Epinephrine) Auto Injector 0.3 Mg |                           |                             | S                        | Transplacental                | 1 Df, Total                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Aug-2015  | 11057271                                  | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2015M1012658     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Jr. Auto-Injector                  |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Aug-2015  | 11347152                                  | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2015M1025769     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Pallor; Poor Peripheral Circulation | Epipen                                    |                           |                             | S                        | Intramuscular                 |                               |                          | Mylan               |                         |

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| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|-----------------------------|----------------------|-----------------|------------|----------------|
| 10-Aug-2015  | 11368010                 | DIRECT             |                    | DS, HO, LT      |                             |                      | 52 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Bacterial Infection; Mobility Decreased; Necrotising Fasciitis | Epipen                   |                    |                    | S               | Intramedullar (bone marrow) |                      |                 |            |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Aug-2015  | 11365962                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1023869   |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration                                      | Epipen                   |                    |                    | S               |                             | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Aug-2015  | 11370981                 | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2015M1026647   |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Tremor   | Epipen                   |                    |                    | S               |                             | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Aug-2015  | 11362637                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1025871   |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular               | 0.15 Mg, Once        |                 |            | Mylan          |
|  | Epipen Jr. Auto-Injector |                    |                    | S               |                             |                      |                 |            | Mylan          |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>        | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Aug-2015  | 11389168                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1026847   |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|  |                          |                    |                    |                 |                             |                      |                 |            |                |

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|  |                          |                    |                    |                 |                           |                      |                 |            |                |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure   | Epipen Jr. Auto-Injector | S                  | Intramuscular      | 0.15 Mg, Once   |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Aug-2015  | 11389176                 | EXPEDITED (15-DAY) |                    | OT              | FI-MYLANLABS-2015M1027384 |                      |                 | Unknown    | FIN            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Jr                |                    |                    | S               |                           |                      |                 |            | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Aug-2015  | 11409486                 | DIRECT             |                    |                 |                           |                      |                 | Unknown    |                |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Reaction To Excipient  | Epi-Pen Auvi-Q           |                    |                    | S               |                           |                      |                 |            |                |
|  |                          |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Aug-2015  | 11409732                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1028225 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising; Injection Site Laceration   | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 |            | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Aug-2015  | 11420106                 | DIRECT             |                    | OT              |                           |                      | 41 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction; Expired Product Administered; Heart Rate Increased; Heart Rate Increased; Injection Site Pain; Injury Associated With Device; Needle Issue | Epipen Jr                |                    |                    | S               |                           |                      |                 |            |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 27-Aug-2015              | 11422418             | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2015M1028396 |                      | 11 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

| <u>FDA Received Date</u>    | <u>Case #</u>      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------|--------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|------------|----------------|
| 28-Aug-2015                 | 9359827            | EXPEDITED (15-DAY) |                    | OT              | CA-ROCHE-1205168                      |                      | 37 YR           | Female     | CAN            |
| <u>Preferred Term</u>       | <u>Product</u>     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Aphonia; Arthropathy;       | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Diarrhoea; Dizziness;       | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Fatigue; Food Allergy;      | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Headache;                   | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Hypoaesthesia; Infected     | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Skin Ulcer; Infusion        | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Related Reaction;           | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Laryngitis; Mouth Swelling; | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Nasopharyngitis; Oedema     | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Peripheral; Oropharyngeal   | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Pain; Oxygen Saturation     | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Decreased; Pruritus;        | Actemra            |                    |                    | S               | Intravenous (not otherwise specified) |                      |                 |            |                |
| Rheumatoid Arthritis;       | Epipen             |                    |                    | S               | Unknown                               |                      |                 |            |                |
| Sialoadenitis; Tongue       | Prednisone         |                    |                    | C               |                                       |                      |                 |            |                |
| Discomfort; White Blood     | Hydroxychloroquine |                    |                    | C               |                                       |                      |                 |            |                |
| Cell Count Increased        | Palafer            |                    |                    | C               |                                       |                      |                 |            |                |
|                             | Arava              |                    |                    | C               |                                       |                      |                 |            |                |
|                             | Sulfasalazine      |                    |                    | C               |                                       |                      |                 |            |                |
|                             | Celebrex           |                    |                    | C               |                                       |                      |                 |            |                |
|                             | Tylenol            |                    |                    | C               |                                       |                      |                 |            |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 31-Aug-2015              | 11434990       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1028256 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                                       |                      |                    |                    |                 |                           |                      |                 |            |                |
|---------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure                        | Epipen Auto-Injector |                    | S                  | Intramuscular   | 0.3 Mg, Prn               |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Sep-2015                           | 11458663             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1028899 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective      | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Sep-2015                           | 11419073             | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2015M1027888 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                        | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Sep-2015                           | 11469842             | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2015M1029077 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                        | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Sep-2015                           | 11469860             | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2015M1023959 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Product Quality Issue | Epipen               |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Sep-2015                           | 11469869             | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2015M1029851 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|   |   |                    |                    |                 |                           |                          |                 |            |                |
|---|---|--------------------|--------------------|-----------------|---------------------------|--------------------------|-----------------|------------|----------------|
| Drug Ineffective; Expired Product Administered  |   | Epipen             |                    | S               |                           | Mylan                    |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Sep-2015   | 11482577                                  | DIRECT             |                    | HO, LT          |                           |                          | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Arrhythmia; Migraine; Myocardial Necrosis Marker Increased; Nuclear Magnetic Resonance Imaging Abnormal | Epi Pen Unk Unk                           |                    |                    | S               | Intramuscular             | Hospital Unk At Hospital |                 |            |                |
|   | Ziac                                      |                    |                    | C               |                           |                          |                 |            |                |
|   | Wellbutrin                                |                    |                    | C               |                           |                          |                 |            |                |
|   | Lisinopril                                |                    |                    | C               |                           |                          |                 |            |                |
|   | Clonapan                                  |                    |                    | C               |                           |                          |                 |            |                |
|   | Biotin                                    |                    |                    | C               |                           |                          |                 |            |                |
|   | Vitamin C                                 |                    |                    | C               |                           |                          |                 |            |                |
|   | Vitamin D3                                |                    |                    | C               |                           |                          |                 |            |                |
|   | Fish Oil                                  |                    |                    | C               |                           |                          |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Sep-2015   | 11498051                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1029595 |                          |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk              |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Sep-2015   | 11496209                                  | EXPEDITED (15-DAY) |                    | DE, HO          | AU-MYLANLABS-2015M1030858 |                          |                 | Unknown    | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Expired Product Administered   | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                      |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Sep-2015   | 11503552                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1029798 |                          |                 | Unknown    | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Injury Associated With Device   | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Sep-2015   | 11503556                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1029922 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Injection Site Bruising   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Sep-2015   | 11517500                 | EXPEDITED (15-DAY) |                    | HO, OT          | CA-MYLANLABS-2015M1028271 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered  | Epipen                   |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |
|   | Epipen                   |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Sep-2015   | 11520443                 | DIRECT             |                    |                 |                           |                      | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; Inability To Afford Medication; Product Quality Issue; Stress | Epi Pen Jr               |                    |                    | S               |                           | Into The Outer Thigh |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Sep-2015   | 11467958                 | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2015M1029301 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen                   |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Sep-2015  | 11522271                                     | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1030601 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector                         |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Sep-2015  | 11529421                                     | EXPEDITED (15-DAY) |                    | DE              | JP-MYLANLABS-2015M1032067 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death  | Epipen                                       |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Sep-2015  | 11537761                                     | EXPEDITED (15-DAY) |                    | OT              | DK-MYLANLABS-2015M1031094 |                      |                 | Unknown    | DNK            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen                                       |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Sep-2015  | 11540006                                     | EXPEDITED (15-DAY) |                    | HO              | AU-MYLANLABS-2015M1032565 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction;<br>Device Failure; Expired<br>Device Used | Epipen (Epinephrine) Auto<br>Injector 0.3 Mg |                    |                    | S               |                           | 300 Mg, Unk          |                 | Mylan      |                |
|  | Epipen (Epinephrine) Auto<br>Injector 0.3 Mg |                    |                    | S               |                           | 300 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Sep-2015  | 11547308                                     | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2015M1031344 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

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|                                  |                      |                    |                    |                 |                           |                      |                 |            |                |
|----------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective                 | Epipen Auto-Injector | S                  | Intramuscular      | 0.3 Mg, Once    | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Sep-2015                      | 11547399             | EXPEDITED (15-DAY) | HO                 |                 | FI-MYLANLABS-2015M1032069 |                      |                 | Unknown    | FIN            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                   | Epipen Jr            |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Sep-2015                      | 11539562             | EXPEDITED (15-DAY) | DE                 |                 | JP-MYLANLABS-2015M1032585 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death                            | Epipen               |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Sep-2015                      | 11564067             | EXPEDITED (15-DAY) | OT                 |                 | US-MYLANLABS-2015M1031554 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective | Epipen Auto-Injector |                    |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Sep-2015                      | 11573029             | EXPEDITED (15-DAY) | OT                 |                 | BE-MYLANLABS-2015M1032419 |                      |                 | Unknown    | BEL            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue     | Epipen               |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
|                                  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Oct-2015                      | 10593127             | EXPEDITED (15-DAY) | HO, OT             |                 | US-MYLANLABS-2014M1011094 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                       |                      |                    |                 |                           |                      |                    |                 |                |
|--|-----------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| Injury Associated With Device  |                       | Epipen Auto-Injector |                    | S               | Unk                       |                      | Mylan              |                 |                |
|  |                       | Epipen Auto-Injector |                    | S               | 0.3 Mg, Prn               |                      | Mylan              |                 |                |
| <u>FDA Received Date</u>   | <u>Case #</u>         | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 02-Oct-2015  | 11590265              | EXPEDITED (15-DAY)   |                    | LT              | DK-MYLANLABS-2015M1032976 |                      |                    | Unknown         | DNK            |
| <u>Preferred Term</u>  | <u>Product</u>        |                      | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Device Failure   | Epipen                |                      |                    |                 | S                         | Intramuscular        |                    |                 | Mylan          |
|  | Alk Engrotteahale 225 |                      |                    |                 | C                         |                      |                    |                 |                |
|  | Bricanyl              |                      |                    |                 | C                         |                      |                    |                 |                |
|  | Aerius                |                      |                    |                 | C                         |                      |                    |                 |                |
|  | Prednisolon           |                      |                    |                 | C                         |                      |                    |                 |                |
|  | Solu-Medrol           |                      |                    |                 | C                         |                      |                    |                 |                |
|  | Tavegyl               |                      |                    |                 | C                         |                      |                    |                 |                |
| <u>FDA Received Date</u>   | <u>Case #</u>         | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 02-Oct-2015  | 11590270              | EXPEDITED (15-DAY)   |                    | HO              | JP-MYLANLABS-2015M1033471 |                      |                    | Unknown         | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>        |                      | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product By Child; Expired Product Administered; Injection Site Pallor | Epipen                |                      |                    |                 | S                         |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>         | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 06-Oct-2015  | 11599172              | EXPEDITED (15-DAY)   |                    | OT              | AT-MYLANLABS-2015M1031522 |                      |                    | Unknown         | AUT            |
| <u>Preferred Term</u>  | <u>Product</u>        |                      | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Device Failure; Device Malfunction   | Epipen                |                      |                    |                 | S                         |                      |                    |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>         | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 07-Oct-2015  | 11608428              | EXPEDITED (15-DAY)   |                    | OT              | US-MYLANLABS-2015M1032756 |                      |                    | Unknown         | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Oct-2015   | 11623456             | DIRECT             |                    |                 |                           |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Label Confusion   | Epipen               |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2015   | 11618870             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1033156 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Apathy; Attention Deficit/Hyperactivity Disorder; Condition Aggravated; Heart Rate Increased; Injection Site Pallor; Mood Altered; Panic Attack | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Xanax                |                    |                    | C               |                           | 0.5 Mg, Qd           |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Oct-2015   | 11629410             | DIRECT             |                    | RI              |                           |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Extra Dose Administered; Needle Issue; Syringe Issue; Syringe Issue   | Epi-Pen              |                    |                    | S               |                           |                      |                 |            |                |
|   | Xyzal                |                    |                    | C               |                           |                      |                 |            |                |
|   | Flovent              |                    |                    | C               |                           |                      |                 |            |                |
|   | Ventolin             |                    |                    | C               |                           |                      |                 |            |                |
|   | Myralax              |                    |                    | C               |                           |                      |                 |            |                |
|   | Align                |                    |                    | C               |                           |                      |                 |            |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 14-Oct-2015   | 11629769   | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2015M1034652 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Decreased; Headache; Hypoaesthesia; Paraesthesia | Epipen   |                    |                    | S               | Intramuscular             | 0.3 Mg, Single       |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Oct-2015   | 11634534   | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1033843 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector                                     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Oct-2015   | 11603941   | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1033554 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective                                | Epipen Auto-Injector                                     |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Oct-2015   | 11640261   | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2015M1035805 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Malaise; Paraesthesia Oral                                      | Epipen (Epinephrine) Auto Injector 0.3 Mg Hydrocortisone |                    |                    | S               |                           | 1 Df, Unk            |                 | Mylan      |                |
|   |  |                    |                    | C               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Oct-2015   | 11641792   | EXPEDITED (15-DAY) |                    | HO              | ZA-MYLANLABS-2015M1034494 |                      |                 | Unknown    | ZAF            |



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| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure  | Epipen Auto-Injector     |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Oct-2015   | 11579688                 | EXPEDITED (15-DAY)        |                             | HO                       | JP-MYLANLABS-2015M1032705     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Blood Pressure Increased; Pain  | Epipen                   |                           |                             | S                        | Intramuscular                 | 1 Df, Single                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Oct-2015   | 11648197                 | DIRECT                    |                             | OT                       |                               |                               | 69 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Malfunction; Device Use Error; Needle Issue                        | Epipen                   |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Oct-2015   | 10368760                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2014S1015998     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Laceration; Scar; Wrong Technique In Product Usage Process | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | .15 Mg,Once                   |                          | Mylan               |                         |
|   | Epipen Jr. Auto-Injector |                           |                             | S                        |                               |                               | Mylan                    |                     |                         |
|   | Multivitamin             |                           |                             | C                        |                               |                               | Unk                      |                     |                         |
|   | Fish Oil                 |                           |                             | C                        |                               |                               | Unk                      |                     |                         |
|   | Melatonin                |                           |                             | C                        |                               |                               | Unk                      |                     |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Oct-2015   | 10419847                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2014S1016002     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|   |                |                          |                    |                 |                               |                      |                 |            |                |
|---|----------------|--------------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Injection Site Laceration;<br>Wrong Technique In<br>Product Usage Process     |                | Epipen Jr. Auto-Injector |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Oct-2015   | 11644780       | EXPEDITED (15-DAY)       |                    | OT              | US-MYLANLABS-<br>2014M1003347 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration;<br>Wrong Technique In<br>Product Usage Process     |                | Epipen Jr. Auto-Injector |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Oct-2015   | 11650703       | EXPEDITED (15-DAY)       |                    | OT              | US-MYLANLABS-<br>2014M1003351 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With<br>Device  |                | Epipen Jr. Auto-Injector |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Oct-2015   | 11650738       | EXPEDITED (15-DAY)       |                    | OT              | US-MYLANLABS-<br>2014S1016280 |                      | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injury Associated<br>With Device           |                | Epipen Jr. Auto-Injector |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Oct-2015   | 11650739       | EXPEDITED (15-DAY)       |                    | OT              | US-MYLANLABS-<br>2014M1003352 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With<br>Device; Wrong Technique<br>In Product Usage Process |                | Epipen Auto-Injector     |                    | S               |                               | Intramuscular        | Unk             | Mylan      |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 21-Oct-2015   | 11650741                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1003353 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device   | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Oct-2015   | 11650742                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1016257 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Eating Disorder; Injection Site Laceration; Injection Site Scar; Post-Traumatic Stress Disorder | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Oct-2015   | 11650744                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014S1016260 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration   | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Oct-2015   | 11451893                 | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2015M1029168 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injury Associated With Device  | Epipen Jr                |                    |                    | S               | Intramuscular             | Unk Unk, Prn         |                 | Mylan      |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 26-Oct-2015  | 11469867                | EXPEDITED (15-DAY)        |                             | OT                       | FR-MYLANLABS-2015M1030213     |                               |                          | Unknown             | FRA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                                     | Epipen                  |                           |                             | S                        |                               | 0.15 Mg / 0.3 MI              |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2015  | 11663366                | DIRECT                    |                             |                          |                               |                               | 2 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Medical Device Site Laceration; Scar               | Epipen Jr 0.15          |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2015  | 11663379                | DIRECT                    | Y                           |                          |                               |                               | 3 YR                     | Male                |                         |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Keloid Scar; Medical Device Site Laceration        | Epipen Jr 0.15 Mg       |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2015  | 11664093                | DIRECT                    | Y                           |                          |                               |                               | 3 YR                     | Unknown             |                         |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Medical Device Site Laceration; Needle Issue; Scar | Epipen                  |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2015  | 11664102                | DIRECT                    | Y                           |                          |                               |                               | 11 YR                    | Male                |                         |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|  |                         |                           |                             |                          |                               |                               |                          |                     |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Device Malfunction;  
Medical Device Site  
Laceration; Needle Issue

Epipen

S

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Oct-2015                       | 11664114               | DIRECT                    | Y                           |                          |                               |                               | 3 YR                | Male                |                         |

| <a href="#">Preferred Term</a>                           | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Medical Device Site<br>Laceration; Needle Issue;<br>Scar | Epipen                  |                       |                     | S                    |                       |                             |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Oct-2015                       | 11664135               | DIRECT                    |                             |                          |                               |                               | 3 YR                | Male                |                         |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Medical Device Site<br>Laceration; Scar; Wrong<br>Technique In Product<br>Usage Process | Epipen                  |                       |                     | S                    |                       |                             |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Oct-2015                       | 11664292               | DIRECT                    | Y                           |                          |                               |                               | 2 YR                | Male                |                         |

| <a href="#">Preferred Term</a>          | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Medical Device Site<br>Laceration; Scar | Epipen                  |                       |                     | S                    |                       |                             |                          |                     |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Oct-2015                       | 11664303               | DIRECT                    | Y                           |                          |                               |                               | 5 YR                | Male                |                         |

| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Medical Device Site<br>Laceration; Wrong<br>Technique In Product | Epipen                  |                       |                     | S                    |                       |                             |                          |                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

## Usage Process

| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 26-Oct-2015   | 11664831                | DIRECT                    | Y                           |                          |                               |                               | 4 YR                     | Male                |                         |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Medical Device Site Laceration; Scar  | Epipen                  |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2015   | 11672157                | DIRECT                    | Y                           |                          |                               |                               | 2 YR                     | Male                |                         |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Injury; Laceration; Wrong Technique In Product Usage Process | Epipen Jr               |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2015   | 11672287                | DIRECT                    | Y                           |                          |                               |                               | 1 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyskinesia; Injection Site Injury; Laceration; Needle Issue; Scar           | Epipen Jr               |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2015   | 11672342                | DIRECT                    | Y                           |                          |                               |                               | 1 YR                     | Male                |                         |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Injury; Laceration; Needle Issue                             | Epipen                  |                           |                             | S                        |                               |                               |                          |                     | Mylan                   |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 29-Oct-2015              | 11682266      | EXPEDITED (15-DAY) |                    | DE              | AU-MYLANLABS-2015M1037677 |                      |            | Unknown    | AUS            |

| <u>Preferred Term</u> | <u>Product</u>                            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Anaphylactic Reaction | Epipen (Epinephrine) Auto Injector 0.3 Mg |              |            | S           | Intramuscular | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 30-Oct-2015              | 11404136      | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2015M1022564 |                      |            | Unknown    | FRA            |

| <u>Preferred Term</u>   | <u>Product</u>        | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|-----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Arthralgia; Inflammation; Intentional Product Misuse; Myalgia | Epipen Jr             |              |            | S           |              | 1 Df, Unk          |                 | Mylan      |
|   | Cortisone             |              |            | C           |              |                    |                 |            |
|   | Lansoprazole          |              |            | C           |              | 60 Mg, Qd          |                 |            |
|   | Mizollen              |              |            | C           |              | 20 Mg, Qd          |                 |            |
|   | Pantoprazole          |              |            | C           |              | 80 Mg, Qd          |                 |            |
|   | Montelukast           |              |            | C           |              | 10 Mg, Qd          |                 |            |
|   | Primalan              |              |            | C           |              | 10 Mg, Qd          |                 |            |
|   | Terbutalin /00199201/ |              |            | C           |              | Unk, Tid           |                 |            |
|   | Valaciclovir          |              |            | C           |              | 1000 Mg, Qd        |                 |            |
|   | Ventolin /00139501/   |              |            | C           |              | Unk, Prn           |                 |            |
|   | Budesonide            |              |            | C           |              | Unk, Tid           |                 |            |
|   | Prednisone            |              |            | C           |              | 7 Mg, Qd           |                 |            |
|   | Tramadol              |              |            | C           |              | 300 Mg, Qd         |                 |            |
|   | Innovair              |              |            | C           |              | 2 Unk, Bid         |                 |            |
|   | Kaleorid              |              |            | C           |              | 600 Mg, Qd         |                 |            |
|   | Fexofenadine          |              |            | C           |              | 360 Mg, Qd         |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 02-Nov-2015              | 11690279      | EXPEDITED (15-DAY) |                    | OT              | IE-MYLANLABS-2015M1036523 |                      |            | Unknown    | IRL            |

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| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|------------------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure  | Epipen                             |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Nov-2015   | 11692365                           | DIRECT                    |                             | DS, HO, LT, RI           |                               |                               | 16 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Reaction;<br>Necrotising Myositis;<br>Septic Shock | Epi Pen Mylan                      |                           |                             | S                        | Intramuscular                 | One Time Use                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Nov-2015   | 11694758                           | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2015M1038198     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthma; Chest Pain  | Epipen                             |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Nov-2015   | 11696338                           | EXPEDITED (15-DAY)        |                             | DE                       | JP-MYLANLABS-2015M1037549     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death   | Epipen                             |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Nov-2015   | 11705939                           | EXPEDITED (15-DAY)        |                             | LT                       | AU-MYLANLABS-2015M1039006     |                               |                          | Unknown             | AUS                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>            | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Jr Adrenaline Auto-Injector |                           |                             | S                        | Intramuscular                 | 150 Mg, Unk                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>             | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 09-Nov-2015   | 11716512                           | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2015M1038056     |                               |                          | Unknown             | USA                     |



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| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective; Wrong Technique In Product Usage Process   | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | 0.3 Mg, Once         |                 | Mylan      |                |
|  | Depakote             |                    |                    | C               | Oral                      | Unk                  |                 |            |                |
|  | Zoloft               |                    |                    | C               | Oral                      | Unk                  |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Nov-2015  | 11512409             | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2015M1031515 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Off Label Use; Product Quality Issue  | Epipen               |                    |                    | S               | Intramuscular             | 0.15 Mg, As Needed   |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Nov-2015  | 11719354             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1033198 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Nov-2015  | 11719378             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1037250 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pain; Injury Associated With Device | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Nov-2015  | 11742283             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1038501 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                      |                          |                    |                 |                           |                      |                 |            |                |  |
|--|----------------------|--------------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|--|
| Device Failure   |                      | Epipen Jr. Auto-Injector |                    | S               | Intramuscular             |                      | 0.15 Mg, Once   |            | Mylan          |  |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 16-Nov-2015  | 11743616             | EXPEDITED (15-DAY)       |                    | OT              | US-MYLANLABS-2015M1039455 |                      |                 | Unknown    | USA            |  |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure; Drug Ineffective   | Epipen Auto-Injector |                          |                    | S               |                           | Unk                  |                 | Mylan      |                |  |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 16-Nov-2015  | 11743932             | EXPEDITED (15-DAY)       |                    | DE, LT, OT      | AU-PFIZER INC-K201000918  |                      | 49 YR           | Female     | AUS            |  |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Clostridial Infection; Crepitations; Gas Gangrene; Injection Site Infection; Injection Site Pain; Purulence; Sepsis; Skin Discolouration | Epipen               |                          |                    | S               | Intramuscular             | 0.3 Mg, Single       |                 | Pfizer     |                |  |
|  | Promethazine         |                          |                    | S               |                           | 50 Mg, Single        |                 |            |                |  |
|  | Prednisolone         |                          |                    | C               |                           | 50 Mg, Unk           |                 |            |                |  |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Nov-2015  | 11347153             | EXPEDITED (15-DAY)       |                    | OT              | FR-MYLANLABS-2015M1025916 |                      |                 | Unknown    | FRA            |  |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure; Needle Issue   | Epipen               |                          |                    | S               |                           |                      |                 | Mylan      |                |  |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>         | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 18-Nov-2015  | 11751927             | EXPEDITED (15-DAY)       |                    | OT              | US-MYLANLABS-2015M1038928 |                      |                 | Unknown    | USA            |  |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>             | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure   | Epipen Auto-Injector |                          |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |  |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Nov-2015  | 11755502                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1031176 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Increased; Expired Product Administered; Heart Rate Increased; Injection Site Pain; Injury Associated With Device | Epipen Jr. Auto-Injector                  |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Nov-2015  | 11753840                                  | EXPEDITED (15-DAY) |                    | HO, LT          | AU-MYLANLABS-2015M1041043 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               | Intramuscular             | 300 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Nov-2015  | 11701720                                  | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2015M1038464 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Product Quality Issue; Wrong Technique In Product Usage Process   | Epipen                                    |                    |                    | S               | Intramuscular             | 0.15 Mg, Single      |                 | Mylan      |                |
|  | Alesion                                   |                    |                    | C               | Oral                      | 12 Mg, Total         |                 |            |                |
|  | Sultanol                                  |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Predonine /00016201/                      |                    |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Nov-2015  | 11457256                                  | NON-EXPEDITED      |                    |                 | PHEH2014US012092          |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

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|  |                      |   |             |                        |          |
|--|----------------------|---|-------------|------------------------|----------|
| Allergy To Arthropod Sting; Balance Disorder; Dizziness; Gait Disturbance; Influenza Like Illness; Malaise; Memory Impairment; Off Label Use; Product Adhesion Issue; Seborrhoea | Exelon Patch         | S | Transdermal | 1 Df (4.6 Mg), Per Day | Novartis |
|  | Exelon Patch         | S | Transdermal | 9.5 Mg, Unk            | Novartis |
|  | Epipen               | S | Unknown     |                        |          |
|  | Cetaphil             | C | Unknown     | Unk Unk, Unk           |          |
|  | Carbidopa Levodopa   | C | Unknown     |                        |          |
|  | Fluticasone          | C | Unknown     |                        |          |
|  | Spironolactone       | C | Unknown     |                        |          |
|  | Pantoprazole         | C | Unknown     |                        |          |
|  | Ropinirole           | C | Unknown     |                        |          |
|  | Sertraline           | C | Unknown     |                        |          |
|  | Valium               | C | Unknown     |                        |          |
|  | Citracal             | C | Unknown     |                        |          |
|  | Vitamin A            | C | Unknown     |                        |          |
|  | Vitamin D3           | C | Unknown     |                        |          |
|  | Coq10                | C | Unknown     |                        |          |
|  | Multi Vitamin        | C | Unknown     |                        |          |
|  | Aspirin              | C | Unknown     |                        |          |
|  | Stool Softener       | C | Unknown     |                        |          |
|  | Miralax              | C | Unknown     |                        |          |
|  | Ginkgo Biloba        | C | Unknown     |                        |          |
|  | Niacin               | C | Unknown     |                        |          |
|  | Vitamin D Nos        | C | Unknown     |                        |          |
|  | Equate Pain Reliever | C | Unknown     |                        |          |
|  | Equate Pain Reliever | C | Unknown     |                        |          |
|  | Fish Oil             | C | Unknown     |                        |          |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 29-Nov-2015              | 11587648       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2015M1032706 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|   |   |                    |                    |                 |                           |                      |                 |            |                |
|---|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Effect Incomplete  |   | Epipen             |                    | S               | Intramuscular             |                      | Unk             | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Nov-2015   | 11789781                                  | DIRECT             | Y                  | OT              |                           |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Pain; Injury Associated With Device | Epi-Pen                                   |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Dec-2015   | 11795081                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2014M1003346 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Scar   | Epipen Jr. Auto-Injector                  |                    |                    | S               |                           | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Dec-2015   | 11805247                                  | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2015M1041818 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               | Intramuscular             | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Dec-2015   | 11824480                                  | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2015M1043103 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Incomplete  | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 |            | Mylan          |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 10-Dec-2015   | 11824491                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1043094 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Increased; Heart Rate Increased; Injection Site Bruising; Injection Site Ischaemia; Injection Site Pain; Injury Associated With Device; Wrong Technique In Product Usage Process | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Dec-2015   | 11389177                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1026654 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2015   | 11849423                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1043912 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Device Failure  | Epipen Auto-Injector     |                    |                    | S               |                           | Prn                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Dec-2015   | 11849429                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1044219 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Scratch  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, 2x          |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Benadryl /00000402/

C

Unk, Once

Mylan

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 21-Dec-2015                       | 11855289               | EXPEDITED (15-DAY)        |                             | DE                       | JP-MYLANLABS-2015M1046125     |                               |                     | Unknown             | JPN                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Neoplasm Malignant             | Epipen                  |                       |                     | S                    | Intramuscular         | 0.3 Mg, Single              |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Dec-2015                       | 11844522               | EXPEDITED (15-DAY)        |                             | OT                       | SE-MYLANLABS-2015M1045265     |                               |                     | Unknown             | SWE                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a>              | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|--|--------------------------|---------------------|
| Device Failure                 | Epipen                  |                       |                     | S                    |                       | Daily Dose: 1 Df Dosage Form Every Total |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 30-Dec-2015                       | 11880079               | EXPEDITED (15-DAY)        |                             | OT                       | IE-MYLANLABS-2015M1047205     |                               |                     | Unknown             | IRL                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure                 | Epipen                  |                       |                     | S                    |                       |                             |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 06-Jan-2016                       | 11893273               | EXPEDITED (15-DAY)        |                             | HO                       | AU-MYLANLABS-2015M1047092     |                               |                     | Unknown             | AUS                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a>                   | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|---|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure                 | Epipen (Epinephrine) Auto Injector 0.3 Mg |                       |                     | S                    |                       | Unk                         |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 13-Jan-2016                       | 11913910               | EXPEDITED (15-DAY)        |                             | OT                       | IE-MYLANLABS-2016M1001907     |                               |                     | Unknown             | IRL                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                |                    |                    |                 |                           |                      |                 |            |                |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Device Malfunction   |                | Epipen             | S                  |                 | 0.3 Mg, Unk               |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Jan-2016  | 11913911       | EXPEDITED (15-DAY) |                    | OT              | IE-MYLANLABS-2016M1001906 |                      |                 | Unknown    | IRL            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen         |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Jan-2016  | 11916130       | EXPEDITED (15-DAY) |                    | OT              | IE-MYLANLABS-2016M1002244 |                      |                 | Unknown    | IRL            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Jan-2016  | 11925218       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2016M1002109 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Increased; Expired Product Administered; Injection Site Pain; Injection Site Pallor; Palpitations | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jan-2016  | 11888531       | EXPEDITED (15-DAY) |                    | HO, LT          | GB-MYLANLABS-2016M1000136 |                      | 48 YR           | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen         |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |
|  | Mebeverine     |                    |                    | C               | Oral                      | 135 Mg, Prn          |                 | Mylan      |                |



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| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|---|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 28-Jan-2016  | 11972278                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1002844 |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Abnormal; Loss Of Consciousness  | Epipen Auto-Injector                      |                    |                    | S               |                           | Unk, 2x   |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jan-2016  | 10755133                                  | EXPEDITED (15-DAY) |                    | HO, LT          | SE-MYLANLABS-2015M1002547 |   |                 | Unknown    | SWE            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective; Needle Issue; Wrong Technique In Product Usage Process     | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               | Intramuscular             | 0.3 Mg, Separate Dosages/ Interval: 4 In 1 Days |                 | Mylan      |                |
|  | Betapred                                  |                    |                    | C               |                           | Unk   |                 | Mylan      |                |
|  | Pulmicort                                 |                    |                    | C               |                           |   |                 | Mylan      |                |
|  | Bricanyl                                  |                    |                    | C               |                           | Unk   |                 | Mylan      |                |
|  | Aerius /01009701/                         |                    |                    | C               |                           | Sep Doses/Interval 4 In 1 Days                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Feb-2016  | 11987229                                  | DIRECT             |                    |                 |                           |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Dispensing Error; Drug Dispensing Error; Drug Ineffective; Expired Product Administered | Epipen Epinephrine                        |                    |                    | S               |                           | Injectable, Injection, Trainer Units            |                 |            |                |
|  | Epipen (Epinephrine)                      |                    |                    | S               |                           | Injectable, Injection                           |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Feb-2016  | 12067293                                  | DIRECT             |                    |                 |                           |   | 4 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                             |                  |   |  |  |  |  |  |  |       |
|-----------------------------|------------------|---|--|--|--|--|--|--|-------|
| Injection Site Bruising;    | Epipen           | S |  |  |  |  |  |  | Mylan |
| Injection Site Pain; Needle | Qvar             | C |  |  |  |  |  |  |       |
| Issue; Needle Issue;        | Albuterol        | C |  |  |  |  |  |  |       |
| Needle Issue; Pain In       | Fluoride Tablets | C |  |  |  |  |  |  |       |
| Extremity                   | Probiotic        | C |  |  |  |  |  |  |       |
|                             | Gummy Vitamin    | C |  |  |  |  |  |  |       |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 15-Feb-2016              | 12077245      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1005155 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure        | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------------|----------------------|------------|------------|----------------|
| 17-Feb-2016              | 9912011       | NON-EXPEDITED    |                    |                 | US-MYLANLABS-PF-2013275228 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Hypersensitivity | Epipen Auto-Injector |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Zoloft               |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Tetracycline         |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Morphine Sulfate     |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Paxil                |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Zofran /00955301/    |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Vitamin B            |              |            | S           |              | Unk                |                 | Mylan      |
|                       | Tetanus Vaccine      |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 17-Feb-2016              | 10822614      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1013629 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure        | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3mg, Prn         |                 | Mylan      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 17-Feb-2016                             | 11458662                 | EXPEDITED (15-DAY)        |                             | HO                       | US-MYLANLABS-2015M1028933     |                               | 19 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dyspnoea                                | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083204                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1010395     |                               | 48 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Eye Swelling            | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083207                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1011977     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083217                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1014345     |                               | 37 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                          | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083221                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1013054     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To                  | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk, Once                     |                          | Mylan               |                         |

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Product; Expired Product  
Administered; Injection  
Site Pain

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 17-Feb-2016                       | 12083225                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1011947     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                    | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                       | 12083226                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1011156     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                    | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                       | 12083227                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1012932     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product    | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk, Once                     |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                       | 12083238                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1000768     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                    | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                       | 12083240                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014M1015837     |                               | 18 YR                    | Male                | USA                     |

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| <a href="#">Preferred Term</a>               | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure                               | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|  | Albuterol /00139501/     |                           |                             | C                        | Respiratory (inhalation)      | Unk, Prn                      |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                  | 12083243                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1000576     |                               | 37 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Expired Product Administered | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|  | Marijuana                |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                  | 12083246                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2014M1016047     |                               | 3 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child      | Epipen Jr. Auto-Injector |                           |                             | S                        | Subcutaneous                  | 0.15 Mg, Unk                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                  | 12083257                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1001495     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product               | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk Unk, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                  | 12083260                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1002676     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product               | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016   | 12083266                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1002233 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event; Off Label Use   | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen Jr. Auto-Injector |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083272                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1002295 |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration   | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083274                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1000326 |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Bruising; Injection Site Injury | Epipen Auto-Injector     |                  |                    | S               |                           | Unk Mg, Unk          |                 | Mylan      |                |
|   | Vitamins /00067501/      |                  |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083276                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1002020 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083277                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1001766 |                      |                 | Unknown    | USA            |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Contusion   | Epipen Trainer           |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016   | 12083278                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1002180     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Pain; Injection Site Pallor; Unevaluable Event | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016   | 12083279                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1008465     |                               | 3 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Pain   | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk Unk                       |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016   | 12083281                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1005546     |                               | 38 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abdominal Pain Upper; Accidental Exposure To Product; Diarrhoea; Nausea; Nervousness; Pyrexia | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016   | 12083293                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1005298     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|  |                      |                      |                    |                 |                           |                      |                 |            |                |
|--|----------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure   |                      | Epipen Auto-Injector |                    | S               |                           | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083301             | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2015M1007045 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Incorrect Route Of Drug Administration | Epipen Auto-Injector |                      |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083306             | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2015M1007904 |                      | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Expired Product Administered  | Epipen Auto-Injector |                      |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083310             | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2015M1009617 |                      | 3 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Swelling       | Epipen Auto-Injector |                      |                    | S               |                           | 0.3 Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083311             | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2015M1008309 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered                           | Epipen Auto-Injector |                      |                    | S               | Intramuscular             | 0.3 Mg Once          |                 | Mylan      |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|---|--|------------------|--------------------|-----------------|---------------------------|--------------------------|-----------------|----------------|----------------|
| 17-Feb-2016   | 12083314                                     | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1005807 |                          | 25 YR           | Male           | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                               | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Expired Product Administered  | Epipen Auto-Injector                         |                  |                    | S               |                           | 0.3 Mg, Unk              |                 | Mylan          |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Feb-2016   | 12083316                                     | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1005422 |                          | 26 YR           | Female         | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                               | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Expired Product Administered; Headache; Injection Site Bruising   | Epipen Auto-Injector<br>Imitrex /01044801/   |                  |                    | S<br>C          | Oral                      | Unk, Once<br>100 Mg, Prn |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Feb-2016   | 12083317                                     | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1002958 |                          | 52 YR           | Female         | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                               | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Discolouration; Injection Site Haemorrhage; Injection Site Hypoaesthesia; Injection Site Pain; Injection Site Swelling; Palpitations; Tremor | Epipen Auto-Injector<br>Epipen Auto-Injector |                  |                    | S<br>S          |                           | 0.3 Mg, Prn              |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                                | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Feb-2016   | 12083318                                     | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1014595 |                          | 62 YR           | Female         | USA            |

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| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Coldness; Injection Site Pain | Epipen Jr. Auto-Injector |                  |                    | S               |                           | 0.15 Mg, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083323                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1013025 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Injury                        | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083343                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1017739 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083344                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1019698 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Auto-Injector     |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083346                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1019735 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Storage Error  | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016  | 12083348             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2015M1021397 |                      | 71 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased;<br>Dry Throat; Dysstasia;<br>Gait Disturbance;<br>Headache; Tremor | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083350             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1016722 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083352             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2015M1016766 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083353             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2015M1018657 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083355             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2015M1018419 |                      |                 | Male       | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083356             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1024462 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083357             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1014775 |                      | 64 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083358             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1014961 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration   | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083363             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1021433 |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Heart Rate Increased; Injection Site Bruising; Injection Site Discolouration; Injection Site Swelling | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016   | 12083364             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1014744 |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Discolouration                    | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083365             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1015588 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Bruising; Injection Site Erythema | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083367             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1015730 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083371             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1015086 |                      | 31 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Bruising   | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083372             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1015941 |                      |                 | Male       | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083375                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1020091 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083379                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1021914 |                      | 4 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Expired Product Administered; Injection Site Coldness; Injection Site Injury | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083380                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1019524 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Incorrect Dose Administered By Device   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083382                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1019910 |                      | 8 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Expired  | Epipen Auto-Injector     |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |

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Product Administered;  
Injection Site  
Haemorrhage; Injection  
Site Injury

| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016  | 12083383                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1020257 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration  | Epipen Auto-Injector     |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083386                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1020080 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083387                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1016357 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Auto-Injector     |                  |                    | S               |                           | Once                 |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083391                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1018949 |                      | 29 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pain; Injection Site Pallor; Maternal Exposure During Pregnancy | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
|  | Iron                     |                  |                    | C               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016  | 12083392                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1021564 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective; Oxygen Saturation Decreased  | Epipen Auto-Injector     |                  |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083396                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1022706 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                  |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083398                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1022964 |                      | 65 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Bruising; Injection Site Haemorrhage; Injection Site Hypoaesthesia; Skeletal Injury | Epipen Auto-Injector     |                  |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
|  | Epipen Auto-Injector     |                  |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083404                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1022117 |                      | 42 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Feeling Jittery; Injection Site Haemorrhage  | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |
|  | Contraceptives           |                  |                    | C               |                           | Unk                  |                 | Mylan      |                |



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| <u>FDA Received Date</u>   | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|--|---|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|----------------|----------------|
| 17-Feb-2016  | 12083408                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1024237 |                      | 46 YR           | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Pain; Musculoskeletal Stiffness   | Epipen Auto-Injector<br>Claritin /00413701/ |                  |                    | S<br>C          |                           | 0.3 Mg, Once         |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Feb-2016  | 12083419                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1017570 |                      | 20 YR           | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Injury Associated With Device  | Epipen Auto-Injector                        |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Feb-2016  | 12083431                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1018363 |                      |                 | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Device Failure   | Epipen Auto-Injector                        |                  |                    | S               | Intramuscular             | 0.3 Unk, Unk         |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                               | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 17-Feb-2016  | 12083433                                    | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1020671 |                      | 6 YR            | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                              | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Accidental Exposure To Product By Child; Injection Site Erythema; Injection Site Injury; Injection Site Pallor | Epipen Jr. Auto-Injector                    |                  |                    | S               | Subcutaneous              | Unk, Once            |                 | Mylan          |                |

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| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016                                      | 12083480             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1027709 |                      | 60 YR           | Male       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered                     | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083481             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1028210 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                   | Epipen Auto-Injector |                  |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083482             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1028043 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                   | Epipen Auto-Injector |                  |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083484             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1026186 |                      | 67 YR           | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; No Adverse Event | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083486             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1028073 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                          |                  |                    |                 |                           |                      |                 |            |                |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure                                   | Epipen Auto-Injector     |                  | S                  |                 |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083487                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1026383 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083490                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1028671 |                      | 1 YR            | Male       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                   | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083491                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1028017 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                   | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083498                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1025410 |                      | 17 YR           | Male       | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; No Adverse Event | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                                      | 12083499                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1027542 |                      |                 | Female     | USA            |

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| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Drug Dispensing Error                   | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083500                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1027437     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product          | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083524                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1031336     |                               | 4 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | 0.15 Mg, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083527                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1028686     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product          | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083535                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1044967     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                          | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                             | 12083536                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1028924     |                               |                          | Female              | USA                     |

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|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Contusion  | Epipen Trainer          |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016  | 12083538                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1038011     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pain In Extremity  | Epipen Trainer          |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016  | 12083541                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1041721     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016  | 12083546                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1029814     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Hypoaesthesia | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk, Once                     |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016  | 12083552                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1033412     |                               | 51 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016  | 12083557                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1034713     |                               |                          | Female              | USA                     |

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| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Skeletal Injury                | Epipen Auto-Injector     |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083560                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1038307 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083561                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1003349 |                      | 1 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Laceration; Injection Site Scar | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083564                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1030287 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Jittery; Palpitations                                  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083565                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1034351 |                      | 4 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child                        | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016   | 12083573                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1044999 |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Heart Rate Increased; Injection Site Hypoaesthesia; Injection Site Pain; Injection Site Paraesthesia; Injection Site Swelling | Epipen Jr. Auto-Injector |                  |                    | S               |                           | 0.15 Mg, Unk         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083574                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1028946 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083575                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1046821 |                      | 79 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Heart Rate Increased  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083576                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1032278 |                      | 8 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Dispensing Error   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Feb-2016   | 12083580                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1039441 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product  | Epipen Auto-Injector     |                  |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083581                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1003350 |                      | 1 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Injection Site Scar; Injury Associated With Device | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083583                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1036789 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083584                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1029327 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain; Unevaluable Event   | Epipen Trainer           |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016   | 12083585                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1032783 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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|   |                          |                  |                    |                 |                           |                      |                 |            |                |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Malaise; Nausea                         | Epipen Auto-Injector     |                  | S                  | Intramuscular   |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                             | 12083589                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1045885 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child | Epipen Jr. Auto-Injector |                  |                    | S               |                           | 1 Df, Once           |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                             | 12083592                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1030797 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Heart Rate Increased                    | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Metoprolol Tartrate      |                  |                    | C               | Oral                      | 10 Mg, Bid           |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                             | 12083593                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2014M1003348 |                      | 11 YR           | Male       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration               | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                             | 12083596                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1031331 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product          | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016                             | 12083597                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1035660 |                      | 2 YR            | Male       | USA            |

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| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Injection Site Laceration                         | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                       | 12083598                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1035081     |                               | 3 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Laceration;<br>Injection Site Scar | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                       | 12083603                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1037558     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity                                  | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | Unk Unk, Prn                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                       | 12083606                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1041419     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                                    | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                       | 12083609                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1044180     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                                    | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Unk                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Feb-2016                                       | 12083611                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1029800     |                               |                          | Female              | USA                     |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| Accidental Exposure To Product; Expired Product Administered | Epipen Auto-Injector |                    |                    | S               |                           | Unk Unk, Once                                 |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083614             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2015M1040270 |   | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Pain | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk, Once                                     |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Feb-2016  | 12083757             | EXPEDITED (15-DAY) |                    | OT              | NL-MYLANLABS-2016M1007328 |   |                 | Unknown    | NLD            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen               |                    |                    | S               |                           |   |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Feb-2016  | 12103083             | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2016M1007048 |   |                 | Unknown    | FRA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Quality Issue                      | Epipen               |                    |                    | S               | Intramuscular             |   |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Feb-2016  | 12111061             | DIRECT             |                    | LT              |                           |   | 21 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue; Product Leakage                | Epipen               |                    |                    | S               |                           | 0.3 Mg, As Needed, Into The Muscle 15 Seconds |                 | Mylan      |                |
|  | Junel                |                    |                    | C               |                           |   |                 |            |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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Bupropion C  
 Prednisone C  
 Benadryl C  
 Pepcid C

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 24-Feb-2016              | 12115013      | DIRECT           |                    | LT              |                      |                      | 20 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>                                   | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|--|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Incorrect Dose Administered By Device; Injection Site Extravasation; Needle Issue; Product Packaging Issue | Epipen 0.3 Mg Mylan Inc.<br>Cymbalta<br>Fish Oil |              |            | S<br>C<br>C | Intramuscular |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 29-Feb-2016              | 12083488      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1026217 |                      | 67 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u> | <u>OTC</u> | <u>Role</u>           | <u>Route</u>                                  | <u>Dosage Text</u>                                      | <u>Duration</u> | <u>Mfr</u>                      |
|--|---|--------------|------------|-----------------------|---|---|-----------------|---------------------------------|
| Drug Effect Decreased; Drug Interaction; Expired Product Administered; Hyperhidrosis; Nausea; Tremor; Vomiting | Epipen Auto-Injector<br>Atenolol<br>Atenolol<br>Benadryl /00000402/<br>Seroquel |              |            | S<br>S<br>S<br>S<br>C | Intramuscular<br>Oral<br>Oral<br>Oral<br>Oral | 0.3 Mg, Once<br>50 Mg, Bid<br>75 Mg, Once<br>200 Mg, Hs |                 | Mylan<br><br><br>Mylan<br>Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Mar-2016              | 12131368      | EXPEDITED (15-DAY) |                    | OT              | NL-MYLANLABS-2016M1009087 |                      |            | Unknown    | NLD            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure        | Epipen Jr      |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 01-Mar-2016              | 12131370      | EXPEDITED (15-DAY) |                    | OT              | NL-MYLANLABS-2016M1009065 |                      |            | Unknown    | NLD            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>            | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|---|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure                            | Epipen (Epinephrine) Auto Injector 0.3 Mg |                           |                             | S                        |                               | 1mg/1ml                       |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>         | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Mar-2016                               | 12131371                                  | EXPEDITED (15-DAY)        |                             | HO                       | GB-MYLANLABS-2016M1009042     |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>            | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthenia; Drug Ineffective; Myalgia       | Epipen                                    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>         | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Mar-2016                               | 12131374                                  | EXPEDITED (15-DAY)        |                             | OT                       | NL-MYLANLABS-2016M1009085     |                               |                          | Unknown             | NLD                     |
| <a href="#">Preferred Term</a>            | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                            | Epipen (Epinephrine) Auto Injector 0.3 Mg |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>         | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Mar-2016                               | 12133156                                  | EXPEDITED (15-DAY)        |                             | HO                       | GB-MYLANLABS-2016M1008789     |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>            | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Compartment Syndrome; Injection Site Pain | Epipen                                    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>         | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Mar-2016                               | 12133343                                  | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1008097     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>            | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injury Associated With Device             | Epipen Auto-Injector                      |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>                                   | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-----------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 01-Mar-2016  | 12137091                          | DIRECT             |                    | HO, LT, OT      |                           |                      | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Decreased; Chest Discomfort; Dyspnoea; Fear | Epipen<br>Epipen<br>Iron          |                    |                    | S<br>C<br>C     |                           |                      |                 |            |                |
| <u>FDA Received Date</u>                                   | <u>Case #</u>                     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Mar-2016  | 12077238                          | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2016M1005433 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                      | <u>Product</u>                    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Effect Incomplete                     | Epipen Auto-Injector              |                    |                    | S               | Intramuscular             | 0.3 Mg, Inject Prn   |                 | Mylan      |                |
|  | Insulin Detemir                   |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Insulin Aspart                    |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Fluticasone                       |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Lorazepam                         |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Levothyroxine                     |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Montelukast                       |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Simvastatin                       |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Hydrocodone                       |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Cyclobenzaprine Hydrochloride     |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Pantoprazole Sodium Sesquihydrate |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Trazodone                         |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Metformin                         |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Lisinopril                        |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Hydroxyzine                       |                    |                    | C               |                           | Unk                  |                 |            |                |
|  | Prednisone                        |                    |                    | C               |                           | Unk                  |                 |            |                |

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| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 11-Mar-2016              | 12171134       | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2016M1010730 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen         |                    |                    | S               |                           |                      |                 |            | Mylan          |

| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 18-Mar-2016   | 11990404                                   | EXPEDITED (15-DAY) |                    | HO, OT          | US-MEDTRONIC-1047217 |                      | 11 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Breakage;<br>Hiccups; Hypertonia;<br>Medical Device Site<br>Fibrosis; Muscle<br>Tightness; Therapeutic<br>Response Decreased | Lioresal Intrathecal (Baclofen Injection)  |                    |                    | S               | Intrathecal          |                      |                 |            | Medtronic      |
|   | Baclofen                                   |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Albuterol                                  |                    |                    | S               |                      |                      |                 |            |                |
|   | Qvar                                       |                    |                    | S               |                      |                      |                 |            |                |
|   | Clonazepam                                 |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Epipen                                     |                    |                    | S               |                      |                      |                 |            |                |
|   | Guar Gum Packet                            |                    |                    | S               |                      |                      |                 |            |                |
|   | Lamotrigine                                |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Lamotrigine                                |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Lansoprazole                               |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Levetiracetam                              |                    |                    | S               |                      |                      |                 |            |                |
|   | Lidocaine                                  |                    |                    | S               | Topical              |                      |                 |            |                |
|   | Nasonex (Mometasone Furoate Monohydrate)   |                    |                    | S               |                      |                      |                 |            |                |
|   | Multivitamin With Iron (Tab-A-Vite W/Iron) |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Omega-3s/Dha/Epa/Fish Oil                  |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Oxycodone Hydrochloride                    |                    |                    | S               |                      |                      |                 |            |                |
|   | Polyethylene Glycol 2250                   |                    |                    | S               | Oral                 |                      |                 |            |                |
|   | Sodium Citrate And Citric Acid             |                    |                    | S               |                      |                      |                 |            |                |
|   | Topiramate                                 |                    |                    | S               |                      |                      |                 |            |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u>                     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|----------------------|--|-----------------|------------|----------------|
| 23-Mar-2016   | 12083915                                       | EXPEDITED (15-DAY) |                    | HO, OT          | PHHY2016US014941     |  |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>                       | <u>Duration</u> | <u>Mfr</u> |                |
| Hiccups; Hypertonia;<br>Medical Device Site<br>Fibrosis; Muscle<br>Tightness; Therapeutic<br>Response Decreased | Lioresal Intratecal                            |                    |                    | S               | Intrathecal          | 50.04 Ug, Qd<br>Concentration 500 Mcg/MI |                 | Novartis   |                |
|   | Lioresal Intratecal                            |                    |                    | S               |                      |  |                 |            |                |
|   | Baclofen                                       |                    |                    | S               | Oral                 | 40 Mg, Qd (In Divided<br>Doses)          |                 |            |                |
|   | Clonazepam                                     |                    |                    | S               | Unknown              | 0.125 Mg, Disintegrating<br>Tablet       |                 |            |                |
|   | Albuterol                                      |                    |                    | S               | Unknown              | 2.5mg/3ml (0.083%) Neb<br>Solution       |                 |            |                |
|   | Beclomethasone//Beclometason<br>e Dipropionate |                    |                    | S               | Unknown              | 80 Ug, Actuation Inhaler                 |                 |            |                |
|   | Epipen   |                    |                    | S               | Unknown              | 0.3mg/0.3ml (1:1,000)                    |                 |            |                |
|   | Guar Gum                                       |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Lactobacillus Acidophilus                      |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Lamictal                                       |                    |                    | S               | Unknown              | 100 Mg, Unk                              |                 |            |                |
|   | Lamictal                                       |                    |                    | S               | Unknown              | 25 Mg, Unk                               |                 |            |                |
|   | Prevacid                                       |                    |                    | S               | Unknown              | 15 Mg, Unk                               |                 |            |                |
|   | Keppra   |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Emla /01389401/                                |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Tab A Vite + Iron                              |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Nasonex  |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Omega 3 Complex /08219501/                     |                    |                    | S               | Oral                 |  |                 |            |                |
|   | Roxicodone                                     |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Polyethylene Glycol                            |                    |                    | S               | Unknown              |  |                 |            |                |
|   | Oracit   |                    |                    | S               | Unknown              | 490-640mg                                |                 |            |                |
|   | Topamax  |                    |                    | S               | Unknown              | 15 Mg, Unk                               |                 |            |                |



# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 31-Mar-2016  | 12208566                 | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2016M1011600 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Apr-2016  | 12229753                 | EXPEDITED (15-DAY) |                    | DE, OT          | AU-MYLANLABS-2016M1013634 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock; Drug Ineffective   | Epipen                   |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Epipen                   |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Apr-2016  | 12233097                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1012453 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Apr-2016  | 12247119                 | EXPEDITED (15-DAY) |                    | OT              | DE-MYLANLABS-2016M1011342 |                      |                 | Unknown    | DEU            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Hypoaesthesia; Injection Site Pallor; Needle Issue; Occupational Exposure To Product; Skin Injury | Epipen                   |                    |                    | S               |                           |                      |                 | Mylan      |                |

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| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 14-Apr-2016  | 12270455                 | DIRECT                    |                             |                          |                               |                               | 4 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child; Injection Site Haemorrhage; Injection Site Pain; Injection Site Pallor; Injury Associated With Device | Epipen Jr                |                           |                             | S                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Apr-2016  | 12273448                 | EXPEDITED (15-DAY)        |                             | HO                       | US-MYLANLABS-2016M1014773     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Apr-2016  | 12297349                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1016128     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Apr-2016  | 12320382                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1016869     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | Unk, Prn                      |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-May-2016  | 12335081                 | EXPEDITED (15-DAY)        |                             | OT                       | FR-MYLANLABS-2016M1018060     |                               |                          | Unknown             | FRA                     |

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| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
|---|---|--------------------|--------------------|-----------------|--|---|-----------------|------------|----------------|
| Administration Site Ischaemia; Medication Error; Wrong Technique In Product Usage Process | Epipen                                    |                    |                    | S               | Intramuscular                            | Daily Dose: 1 Df Dosage Form Every Days |                 | Mylan      |                |
|   | Remicade                                  |                    |                    | C               | Oral                                     |   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-May-2016   | 12335090                                  | EXPEDITED (15-DAY) |                    | OT              | BE-MYLANLABS-2016M1018328                |   |                 | Unknown    | BEL            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Bruising   | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |  |   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-May-2016   | 12335143                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1017197                |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Wrong Technique In Product Usage Process                                  | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular                            | 0.3 Mg, Once                            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                     | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-May-2016   | 12366066                                  | EXPEDITED (15-DAY) |                    | OT              | US-ENDO PHARMACEUTICALS INC.-2016-003170 |   | 58 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                             | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
| Lip Swelling; Urticaria   | Hydrocortisone Tablets                    |                    |                    | S               | Unknown                                  |   |                 |            |                |
|   | Epipen                                    |                    |                    | S               | Unknown                                  |   |                 |            |                |
|   | Zantac                                    |                    |                    | S               | Unknown                                  |   |                 |            |                |
|   | Benadryl                                  |                    |                    | S               | Unknown                                  |   |                 |            |                |
|   | Prednisone                                |                    |                    | S               | Unknown                                  |   |                 |            |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|-----------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 13-May-2016                             | 12368986                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1019214 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthenia; Drug Effect                   | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| Incomplete; Somnolence; Tremor          | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-May-2016                             | 12375548                    | EXPEDITED (15-DAY) |                    | OT              | JP-TEVA-2016-JP-001065J   |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Drug Ineffective | Doxazosin Tablet 4mg "Teva" |                    |                    | S               | Oral                      |                      |                 |            |                |
|   | Epipen                      |                    |                    | S               | Unknown                   |                      |                 |            |                |
| <u>FDA Received Date</u>                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-May-2016                             | 12380824                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1019467 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                          | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-May-2016                             | 12387522                    | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1020180 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                          | Epipen Auto-Injector        |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-May-2016                             | 12388509                    | EXPEDITED (15-DAY) |                    | HO              | JP-MYLANLABS-2016M1020938 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>                   | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                  |            |   |                  |               |       |
|------------------|------------|---|------------------|---------------|-------|
| Gait Disturbance | Epipen     | S | Intramuscular    | Unk, Single   | Mylan |
|                  | Epipen     | S |                  |               | Mylan |
|                  | Saxizon    | S | Intravenous drip | 300 Mg, Daily | Mylan |
|                  | Polaramine | S | Intravenous drip | 5 Mg, Daily   | Mylan |

| <u>FDA Received Date</u>          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 23-May-2016                       | 12393989       | EXPEDITED (15-DAY) |                    | DE              | GB-MYLANLABS-2016M1020994 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock;               | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| Arthropod Sting; Drug Ineffective | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |

| <u>FDA Received Date</u>                   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 23-May-2016                                | 12395485             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1016733 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                      | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Intentional Product Misuse | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 27-May-2016  | 12412212       | EXPEDITED (15-DAY) |                    | OT              | HR-MYLANLABS-2016M1022187 |                      |                 | Unknown    | HRV            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Swelling | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 27-May-2016              | 12413400       | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1021156 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                             |                                 |                    |                    |                 |                           |                           |                      |                 |            |                |
|-----------------------------|---------------------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure              | Epipen Auto-Injector            |                    | S                  |                 | Intramuscular             |                           | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2016                 | 12425806                        | EXPEDITED (15-DAY) |                    | DE              | CA-PFIZER INC-K200601089  |                           |                      | 61 YR           | Male       | CAN            |
| <u>Preferred Term</u>       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock;         | Epipen                          |                    |                    | S               |                           | 0.3 Mg, Single            |                      |                 | Pfizer     |                |
| Angioedema; Cardio-         | Lopressor                       |                    |                    | S               |                           | 100 Mg, 2x/Day            |                      |                 |            |                |
| Respiratory Arrest; Drug    | Accupril                        |                    |                    | C               |                           | 20 Mg, 1x/Day             |                      |                 |            |                |
| Ineffective; Drug           |                                 |                    |                    |                 |                           |                           |                      |                 |            |                |
| Interaction; Dyspnoea;      |                                 |                    |                    |                 |                           |                           |                      |                 |            |                |
| Vomiting                    |                                 |                    |                    |                 |                           |                           |                      |                 |            |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Jun-2016                 | 12428399                        | DIRECT             |                    | LT              |                           |                           |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction;         | Epipen Jr. 2-Pak, 0.15 Mg Mylan |                    |                    | S               | Intramuscular             | 1 Injection (S) As Needed |                      |                 | Mylan      |                |
| Laceration; Medical         | Specialty Lp                    |                    |                    |                 |                           | Into The Muscle           |                      |                 |            |                |
| Device Site Haemorrhage;    | Epipen Jr                       |                    |                    | C               |                           |                           |                      |                 |            |                |
| Medical Device Site Injury; | Albuterol With Chamber          |                    |                    | C               |                           |                           |                      |                 |            |                |
| Needle Issue; Scratch       | Vitamins                        |                    |                    | C               |                           |                           |                      |                 |            |                |
|                             | Probiotics                      |                    |                    | C               |                           |                           |                      |                 |            |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Jun-2016                 | 12436148                        | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1021909 |                           |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration   | Epipen Jr. Auto-Injector        |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn              |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>    | <u>Case #</u>                   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2016                 | 12131372                        | EXPEDITED (15-DAY) |                    | HO              | SE-MYLANLABS-2016M1009056 |                           |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>       | <u>Product</u>                  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        |                      | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                |   |   |  |  |  |  |  |       |
|----------------|---|---|--|--|--|--|--|-------|
| Device Failure | Epipen (Epinephrine) Auto Injector 0.3 Mg | S |  |  |  |  |  | Mylan |
|----------------|---|---|--|--|--|--|--|-------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 06-Jun-2016              | 12179921      | EXPEDITED (15-DAY) |                    | LT              | SE-MYLANLABS-2016M1011075 |                      |            | Unknown    | SWE            |

| <u>Preferred Term</u>               | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-------------------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; Expired Device Used | Epipen         |              |            | S           |              |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>  | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|-----------------------|----------------------|------------|------------|----------------|
| 10-Jun-2016              | 12352886      | NON-EXPEDITED    |                    | OT              | US-MDT-ADR-2016-00495 |                      | 38 YR      | Male       | USA            |

| <u>Preferred Term</u>                        | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------------------|----------------------|-----------------|------------|
| Hypertonia; Muscle Spasms; Pain In Extremity | Lioresal       |              |            | S           | Intrathecal              | 134.3 Mcg/Day.       |                 |            |
|  | Azelastine     |              |            | S           | Nasal                    | 137 Mcg              |                 |            |
|  | Epipen         |              |            | S           |                          |                      |                 |            |
|  | Fluticasone    |              |            | S           | Nasal                    | 50 Mcg/Actuation     |                 |            |
|  | Gabapentin     |              |            | S           | Oral                     |                      |                 |            |
|  | Norco          |              |            | S           | Oral                     | 5-325 Mg             |                 |            |
|  | Levothyroxine  |              |            | S           | Oral                     |                      |                 |            |
|  | Montelukast    |              |            | S           | Oral                     |                      |                 |            |
|  | Lioresal       |              |            | S           | Intrathecal              | 122.12 Mcg/Day       |                 |            |
|  | Advil Pm       |              |            | S           | Oral                     |                      |                 |            |
|  | Albuterol      |              |            | S           | Respiratory (inhalation) | 90 Mcg/Actuation     |                 |            |
|  | Citalopram     |              |            | S           | Oral                     |                      |                 |            |
|  | Simvastatin    |              |            | S           | Oral                     |                      |                 |            |
|  | Loratadine     |              |            | S           | Oral                     | One Tablet As Needed |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 16-Jun-2016              | 12472253      | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-       |                      | 87 YR      | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2016290452

| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective; Feeling Abnormal; Lethargy; Limb Discomfort | Epipen                   |                    |                    | S               | Intramuscular             | 0.3 Mg, 3x           |                 | Pfizer     |                |
|   | Epipen                   |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Jun-2016   | 12486631                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016307187  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen                   |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2016   | 12490245                 | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2016M1025006 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hospitalisation   | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jun-2016   | 12486332                 | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2016307524  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Dyspnoea; Headache; Swelling                | Epipen                   |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jun-2016   | 12500547                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016317774  |                      | 5 YR            | Female     | USA            |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Injection Site Bruising;<br>Product Quality Issue  | Epipen Jr                |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jul-2016  | 12497333                 | EXPEDITED (15-DAY)        |                             | DE                       | US-MYLANLABS-<br>2016M1026505 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Dose Omission   | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jul-2016  | 12522417                 | EXPEDITED (15-DAY)        |                             | HO, OT                   | GB-MYLANLABS-<br>2016M1027593 |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To<br>Product; Wrong Technique<br>In Product Usage Process   | Epipen                   |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jul-2016  | 12522549                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-<br>2016M1026243 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector     |                           |                             | S                        |                               | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 06-Jul-2016  | 12465525                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-<br>2016290871  |                               | 65 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To<br>Product; Expired Product<br>Administered; Injection<br>Site Bruising; Injection Site<br>Coldness; Injection Site | Epipen 0.3mg             |                           |                             | S                        |                               | 0.3 Mg, Injection             |                          | Pfizer              |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypoaesthesia; Injection  
Site Injury; Injection Site  
Pain; Injection Site  
Swelling; Pain In  
Extremity; Palpitations;  
Poor Quality Drug  
Administered; Product  
Quality Issue

| <u>FDA Received Date</u>                          | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 06-Jul-2016                                       | 12531387       | EXPEDITED (15-DAY) |                    | OT              | BE-PFIZER INC-<br>2016248202 |                      | 19 YR           | Female     | BEL            |
| <u>Preferred Term</u>                             | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising;<br>Product Quality Issue | Epipen Jr      |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 06-Jul-2016   | 12531750       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-<br>2016328340 |                      | 6 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product By Child; Injection<br>Site Bruising; Injection Site<br>Haemorrhage; Tremor | Epipen Jr      |                  |                    | S               |                              | 0.15 Mg, Unk         |                 | Pfizer     |                |

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 07-Jul-2016   | 12208563             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-<br>2016M1011793 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Arthritis; Injected<br>Limb Mobility Decreased;<br>Injection Site Pain;<br>Injection Site Pallor;<br>Wrong Technique In<br>Product Usage Process | Epipen Auto-Injector |                    |                    | S               |                               | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>  | <u>Country</u> |
|---|---|--------------------|--------------------|-----------------|----------------------------|-------------------------|-----------------|-------------|----------------|
| 07-Jul-2016   | 12535940                                  | EXPEDITED (15-DAY) |                    | OT              | US-ASTRAZENECA-2016SE72332 |                         |                 | Female      | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>  |                |
| Lip Swelling; Pharyngeal Oedema; Swollen Tongue   | Prilosec Otc                              |                    |                    | S               | Oral                       |                         |                 | Astrazeneca |                |
|   | Epipen                                    |                    |                    | S               | Unknown                    |                         |                 |             |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>  | <u>Country</u> |
| 07-Jul-2016   | 12537619                                  | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2016328555   |                         | 33 YR           | Female      | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>  |                |
| Condition Aggravated; Hypersensitivity; Reaction To Excipient   | Epipen                                    |                    |                    | S               |                            | 0.3 Mg, As Needed (Prn) |                 | Pfizer      |                |
|   | Epipen                                    |                    |                    | S               |                            |                         |                 | Pfizer      |                |
|   | Antibiotic /00011701/                     |                    |                    | C               |                            | Unk                     |                 |             |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>  | <u>Country</u> |
| 08-Jul-2016   | 12540461                                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016334535   |                         |                 | Female      | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>  |                |
| Drug Hypersensitivity   | Epipen                                    |                    |                    | S               |                            | Unk                     |                 | Unknown     |                |
|   | Aspirin                                   |                    |                    | S               |                            | Unk                     |                 |             |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>       | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u>  | <u>Country</u> |
| 11-Jul-2016   | 12393263                                  | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2016M1021175  |                         |                 | Unknown     | FRA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>               | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u>  |                |
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Pain; Injury Associated With Device | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                            |                         |                 | Mylan       |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 11-Jul-2016   | 12506011       | EXPEDITED (15-DAY) |                    | LT              | CZ-MYLANLABS-2016M1026805 |   |                 | Unknown    | CZE            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Loss Of Consciousness   | Epipen         |                    |                    | S               |                           | Daily Dose: 1 Df Dosage Form Every Days |                 | Mylan      |                |
|   | Prednisolone   |                    |                    | C               | Oral                      | 1 Df, Qd                                |                 | Mylan      |                |
|   | Zyrtec         |                    |                    | C               | Oral                      | 2 Df, Qd                                |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Jul-2016   | 12545319       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016176437  |   |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Joint Inflammation; Injection Site Movement Impairment; Injection Site Pain; Injection Site Pallor; Wrong Technique In Product Usage Process | Epipen Jr      |                    |                    | S               |                           | 0.3 Mg, Unk                             |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Jul-2016   | 12546436       | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2016339001  |   |                 | Female     | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Perinatal Depression   | Epipen         |                    |                    | S               |                           | Unk                                     |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2016   | 12548229       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016337447  |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |        |   |     |        |
|--|--------|---|-----|--------|
| Bone Contusion; Gait Disturbance; Injection Site Bruising; Injection Site Discomfort; Injection Site Haematoma; Injection Site Pain; Injection Site Swelling; Insomnia | Epipen | S | Unk | Pfizer |
|--|--------|---|-----|--------|

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 12-Jul-2016              | 12550557       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016337552 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Euphoric Mood            | Epipen         |                  |                    | S               | Unknown                  | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 15-Jul-2016   | 12545198       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2016337611 |                      | 65 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Heart Rate Increased; Injection Site Bruising; Injection Site Coldness; Injection Site Hypoaesthesia; Injection Site Injury; Injection Site Pain; Injection Site Swelling; Pain In Extremity; Palpitations; Product Colour Issue; Product Expiration Date Issue | Epipen         |                  |                    | S               |                          | 0.3 Mg, Unk          |                 | Pfizer     |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 15-Jul-2016              | 12561349       | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2016275509 |                      | 33 YR           | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |           |   |     |        |
|---|-----------|---|-----|--------|
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Injury; Injection Site Pain | Epipen Jr | S | Unk | Pfizer |
|---|-----------|---|-----|--------|

| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 15-Jul-2016                                  | 12563089                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1028275     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Expired Product Administered | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |

| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 19-Jul-2016   | 12570370                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2016347929      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Pain; Wrong Technique In Product Usage Process | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |

| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Jul-2016   | 12577017                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1029017     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Swelling; Palpitations | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Jul-2016                       | 12579083                | EXPEDITED (15-DAY)        |                             | DE, HO                   | AU-MYLANLABS-2016M1030008     |                               |                          | Unknown             | AUS                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                          |  |                    |                    |                 |                           |                      |                 |            |                |
|--------------------------|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Coma; Death              |  | Epipen             |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Jul-2016              | 12580952                                 | EXPEDITED (15-DAY) |                    | HO              | JP-TEVA-2016-JP-001605J   |                      | 15 YR           | Male       | JPN            |
| <u>Preferred Term</u>    | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Gait Disturbance         | Saxizon For Intravenous Injection 1000mg |                    |                    | S               | Intravenous drip          | 300 Milligram Daily; |                 | Teva       |                |
|                          | Epipen                                   |                    |                    | S               | Intramuscular             |                      |                 |            |                |
|                          | Epipen                                   |                    |                    | S               |                           |                      |                 |            |                |
|                          | Polaramine                               |                    |                    | S               | Intravenous drip          | 5 Milligram Daily;   |                 |            |                |
| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Jul-2016              | 12580980                                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1029168 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen Auto-Injector                     |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Jul-2016              | 12581021                                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1029177 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen Auto-Injector                     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>                            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Jul-2016              | 12587793                                 | EXPEDITED (15-DAY) |                    | DE, HO          | AU-PFIZER INC-2016357522  |                      | 15 YR           | Male       | AUS            |
| <u>Preferred Term</u>    | <u>Product</u>                           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Coma; Death              | Epipen                                   |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 25-Jul-2016   | 12588138                       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016357196 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Wrong Technique In Product Usage Process       | Epipen                         |                    |                    | S               |                          | Unk(0.3mg 2 Pack)    |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Jul-2016   | 12589726                       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016356021 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Swelling; Palpitations | Epipen Jr                      |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Jul-2016   | 12596526                       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016361177 |                      | 59 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Condition Aggravated; Hypersensitivity; Reaction To Excipient; Respiratory Distress                 | Epipen                         |                    |                    | S               | Intramuscular            | 0.3 Mg, Unk          |                 | Pfizer     |                |
|   | Metformin                      |                    |                    | C               |                          | Unk                  |                 |            |                |
|   | Armour Thyroid                 |                    |                    | C               |                          | Unk                  |                 |            |                |
|   | Epinephrine /00003902/         |                    |                    | C               |                          | Unk, As Needed       |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jul-2016   | 12596195                       | EXPEDITED (15-DAY) |                    | OT              | US-BAXTER-2016BAX038208  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                 | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Fluid Overload; Meningitis  | 0.9% Sodium Chloride Injection |                    |                    | S               | Unknown                  |                      |                 | Baxter     |                |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|         |   |   |            |                    |  |  |  |  |        |
|---------|---|---|------------|--------------------|--|--|--|--|--------|
| Aseptic | 5% Dextrose And 0.45% Sodium Chloride Injection USP | S | Unknown    |                    |  |  |  |  | Baxter |
|         | Heparin Sodium In 0.9% Sodium Chloride Injection    | S | Unknown    | Strength: 10 lu/MI |  |  |  |  | Baxter |
|         | Ampyra  | S | Oral       |                    |  |  |  |  |        |
|         | Gammagard Liquid                                    | S | Parenteral | Via Infusion       |  |  |  |  |        |
|         | Acetaminophen                                       | S | Unknown    |                    |  |  |  |  |        |
|         | Diphenhydramine Hydrochloride                       | S | Unknown    |                    |  |  |  |  |        |
|         | Epipen  | S | Unknown    |                    |  |  |  |  |        |
|         | Zoloft  | S | Unknown    |                    |  |  |  |  |        |
|         | Vitamin D3  | S | Unknown    |                    |  |  |  |  |        |
|         | Copaxone  | S | Unknown    |                    |  |  |  |  |        |
|         | Ortho Tri-Cyclen                                    | S | Unknown    |                    |  |  |  |  |        |
|         | Spironolactone                                      | S | Unknown    |                    |  |  |  |  |        |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 29-Jul-2016  | 12606731       | EXPEDITED (15-DAY) |                    | HO              | GB-MYLANLABS-2016M1031178 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea; Headache; Loss Of Consciousness; Malaise | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |

| <u>FDA Received Date</u>                                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 29-Jul-2016  | 12607522       | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2014M1008085 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>                                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Ischaemia | Epipen         |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 29-Jul-2016              | 12608575      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1030486 |                      |            | Unknown    | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Aug-2016  | 12613663                | DIRECT                    |                             |                          |                               |                               | 3 YR                     | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Laceration; Needle Issue;<br>Product Quality Issue   | Epi Pen Jr              |                           |                             | S                        | Intramuscular                 |                               |                          |                     |                         |
|  | Singulair               |                           |                             | C                        |                               |                               |                          |                     |                         |
|  | Calcium Supplement      |                           |                             | C                        |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Aug-2016  | 12608581                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2016M1030089     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Injection Site Swelling  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Aug-2016  | 12614824                | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2016368339      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Finger Amputation; Skeletal Injury; Wrong Technique In Product Usage Process | Epipen                  |                           |                             | S                        |                               | Unk, Once                     |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Aug-2016  | 12611438                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-PFIZER INC-2016368608      |                               | 73 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|   |                |                    |                    |                 |                          |                      |                 |            |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective; Injection Site Swelling   |                | Epipen             | S                  | Intramuscular   | 0.3 Mg, Once             | Pfizer               |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Aug-2016   | 12618545       | EXPEDITED (15-DAY) |                    | HO              | GB-PFIZER INC-2016368219 |                      | 25 YR           | Female     | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea; Headache; Loss Of Consciousness; Malaise  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Aug-2016   | 12626642       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2014363426 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Ischaemia; Injection Site Pallor | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Aug-2016   | 12633765       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016375541 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain  | Epipen Jr      |                    |                    | S               | Unknown                  | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2016   | 12607218       | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2016299501 |                      |                 | Male       | CAN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Loss Of Consciousness   | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 09-Aug-2016  | 12635871             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016377284  |                      | 3 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Psychomotor Hyperactivity | Epipen Jr            |                    |                    | S               |                           | 0.15 Mg, Unk         |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2016  | 12635888             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016377282  |                      | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Injury     | Epipen 0.3mg         |                    |                    | S               |                           | Unk, Once            |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Aug-2016  | 12640373             | DIRECT             | Y                  |                 |                           |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Packaging Confusion  | Epipen               |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Aug-2016  | 12641984             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1032446 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Aug-2016  | 12522422             | EXPEDITED (15-DAY) |                    | HO, OT          | FR-MYLANLABS-2016M1027426 |                      |                 | Unknown    | FRA            |

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| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|--|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| Anaphylactic Reaction;<br>Asthma; Device Defective;<br>Device Failure; Drug<br>Ineffective; Loss Of<br>Consciousness; Oxygen<br>Saturation Decreased            | Epipen                                     |                    |                    | S               | Intramuscular                | 0.15mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Aug-2016   | 12647290                                   | DIRECT             |                    | OT              |                              |                      | 51 YR           | Female     | CHE            |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Formulation Issue   | Epipen 0.3 Mg Epinephrine<br>Auto-Injector |                    |                    | S               |                              |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Aug-2016   | 12648788                                   | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2016383227 |                      | 63 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Expired Product<br>Administered; Injection<br>Site Pain; Wrong<br>Technique In Product<br>Usage Process                      | Epipen Jr                                  |                    |                    | S               |                              | Unk, Once            |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Aug-2016   | 12602830                                   | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-<br>2016355045 |                      | 3 YR            | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product By Child; Injection<br>Site Discolouration;<br>Injection Site Injury;<br>Injection Site Ischaemia;<br>Injection Site Swelling | Epipen 0.15mg                              |                    |                    | S               | Intramuscular                | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 15-Aug-2016   | 12653030             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016384984  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain In Extremity; Product Administered At Inappropriate Site             | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2016   | 12655783             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016384981  |                      | 3 YR            | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury; Product Quality Issue                              | Epipen Jr            |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2016   | 12655884             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016386595  |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Aug-2016   | 12665592             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2016M1034189 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Device Failure; Heart Rate Increased; Underdose | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Baclofen             |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|   | Benadryl /00000402/  |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|   | Pepcid /00305201/    |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|   | Bisoprolol           |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Aug-2016   | 12667405                           | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016391923  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain  | Epipen                             |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Aug-2016   | 12668833                           | EXPEDITED (15-DAY) |                    | LT              | AU-MYLANLABS-2016M1034294 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Liquid Product Physical Issue   | Epipen Jr Adrenaline Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Aug-2016   | 12471715                           | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016299631  |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Heart Rate Increased; Limb Injury; Nail Injury; Oxygen Saturation Decreased | Epipen                             |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Aug-2016   | 12680263                           | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2016395898  |                      | 34 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Heart Rate Increased; Product Quality Issue; Underdose                            | Epipen                             |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
|   | Baclofen                           |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Benadryl /00000402/                |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Pepcid /00305201/                  |                    |                    | C               |                           | Unk                  |                 |            |                |

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|   |                      |                    |                    |                 |                           |                      |                 |            |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Bisoprolol  |                      |                    | C                  |                 |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Aug-2016   | 12683646             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016397902  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Laceration | Epipen Jr            |                    |                    | S               |                           | Unk, Once            |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Aug-2016   | 12689498             | EXPEDITED (15-DAY) |                    | OT              | NL-MYLANLABS-2016M1036288 |                      |                 | Unknown    | NLD            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Administration Error   | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |
|   | Desloratadine        |                    |                    | C               |                           |                      |                 | Mylan      |                |
|   | Diclofenac           |                    |                    | C               |                           |                      |                 | Mylan      |                |
|   | Pantazol             |                    |                    | C               |                           |                      |                 | Mylan      |                |
|   | Thyrax /00068001/    |                    |                    | C               |                           |                      |                 | Mylan      |                |
|   | Enalapril            |                    |                    | C               | Topical                   |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Aug-2016   | 12692681             | DIRECT             | Y                  | DS              |                           |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Issue  | Epipen               |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Aug-2016   | 12692701             | DIRECT             |                    |                 |                           |                      | 22 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction; Laceration; Needle Issue;   | Epipen               |                    |                    | S               |                           |                      |                 |            |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Treatment Failure

| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|-------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 30-Aug-2016   | 12697887                      | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016406804  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Erythema; Injection Site Haemorrhage | Epipen                        |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Aug-2016   | 12699112                      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1035440 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector          |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Aug-2016   | 12699955                      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1035955 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered  | Epipen Jr. Auto-Injector      |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
|   | Epipen Jr. Auto-Injector      |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Aug-2016   | 12701170                      | DIRECT             |                    |                 |                           |                      | 59 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Product Expiration Date Issue; Product Label Confusion                              | Epipen                        |                    |                    | S               |                           |                      |                 |            |                |
|   | Enbrel                        |                    |                    | C               |                           |                      |                 |            |                |
|   | Citalopram                    |                    |                    | C               |                           |                      |                 |            |                |
|   | Lorazepam                     |                    |                    | C               |                           |                      |                 |            |                |
|   | Certirizine Equate Brand (Wal |                    |                    | C               |                           |                      |                 |            |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

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Hydroxyzine

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| <u>FDA Received Date</u>       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------------|-------------------|--------------------|--------------------|-----------------|--------------------------|------------------------|-----------------|------------|----------------|
| 31-Aug-2016                    | 12667347          | EXPEDITED (15-DAY) |                    | OT              | US-JAZZ-2016-US-015124   |                        |                 | Male       | USA            |
| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Abuse; Psychotic Disorder | Xyrem             |                    |                    | S               | Oral                     | 2.25 G, Bid            |                 | Jazz       |                |
|                                | Xyrem             |                    |                    | S               | Oral                     | Dose Adjustments       |                 | Jazz       |                |
|                                | Xyrem             |                    |                    | S               | Oral                     | 4.5 G, Bid             |                 | Jazz       |                |
|                                | Dextroamphetamine |                    |                    | S               |                          | Unk                    |                 |            |                |
|                                | Epipen            |                    |                    | S               |                          |                        |                 |            |                |
|                                | Nuvigil           |                    |                    | C               |                          | Unk                    |                 |            |                |
| <u>FDA Received Date</u>       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Aug-2016                    | 12704334          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016408677 |                        |                 | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising        | Epipen            |                    |                    | S               |                          | Unk                    |                 | Pfizer     |                |
| <u>FDA Received Date</u>       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Sep-2016                    | 12706488          | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2016406312 |                        |                 | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective               | Epipen            |                    |                    | S               | Intramuscular            | 0.3 Mg, As Needed, Prn |                 | Pfizer     |                |
| <u>FDA Received Date</u>       | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Sep-2016                    | 12707720          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016412688 |                        |                 | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Tachycardia                    | Epipen            |                    |                    | S               |                          | Unk                    |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

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### Detailed Report

| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 02-Sep-2016                                  | 12712514          | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2016412670  |                      | 56 YR           | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                             | Epipen            |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2016                                  | 12711772          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016412684  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Screen False Positive                   | Epipen            |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2016                                  | 12717349          | DIRECT             | Y                  | LT              |                           |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Injection Site Haemorrhage | Epipen 0.3% Mylan |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2016                                  | 12717783          | EXPEDITED (15-DAY) |                    | OT              | FI-MYLANLABS-2016M1037320 |                      |                 | Unknown    | FIN            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                               | Epipen            |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2016                                  | 12717926          | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2016416659  |                      | 82 YR           | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                             | Epipen            |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---------------------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 07-Sep-2016   | 12721806                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1037327 |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anaphylactic Reaction; Device Failure                               | Epipen Auto-Injector      |                    |                    | S               |                           | 0.3 Mg, Prn   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2016   | 12722434                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1037295 |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered  | Epipen Auto-Injector      |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Sep-2016   | 12722445                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1037385 |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered; Injury Associated With Device; Loss Of Consciousness; Skeletal Injury | Epipen Auto-Injector      |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Sep-2016   | 12728949                  | DIRECT             |                    | HO              |                           |   | 79 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction  | Epipen. Lot #6gmo71 Mylan |                    |                    | S               |                           | Other Strength;;Other Dose;;Other Frequency;;Other Route:Injection Failed |                 | Mylan      |                |
|   | Citalopram                |                    |                    | C               |                           |   |                 |            |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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|   |                      |                    |                    |                 |                           |                      |                    |                 |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| Amlodipine  |                      |                    | C                  |                 |                           |                      |                    |                 |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 09-Sep-2016   | 12717354             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016401205  |                      |                    | Female          | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Hypersensitivity   | Epipen               |                    |                    |                 | S                         |                      | Unk                |                 | Pfizer         |
|   | Proair               |                    |                    |                 | S                         |                      | Unk                |                 |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 09-Sep-2016   | 12728885             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2016422511  |                      | 29 YR              | Female          | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Accidental Exposure To Product; Drug Ineffective; Product Quality Issue   | Epipen               |                    |                    |                 | S                         |                      | 0.3 Mg, Prn        |                 | Pfizer         |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 09-Sep-2016   | 12730229             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1037787 |                      |                    | Unknown         | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Device Failure  | Epipen Auto-Injector |                    |                    |                 | S                         | Intramuscular        | 0.3 Mg, Prn        |                 | Mylan          |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 12-Sep-2016   | 12735476             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016422509  |                      | 63 YR              | Male            | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Administration Error; Expired Product Administered; Foreign Body; Loss Of Consciousness; Product Quality Issue; Skeletal | Epipen               |                    |                    |                 | S                         | Intramuscular        | 0.3 Mg, Prn        |                 | Pfizer         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Injury

| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 12-Sep-2016                                  | 12736050                | EXPEDITED (15-DAY)        |                             | OT                       | JP-PFIZER INC-2016420884      |                               | 75 YR                    | Female              | JPN                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated; Malaise; Seizure       | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Sep-2016                                  | 12739036                | EXPEDITED (15-DAY)        |                             | HO, OT                   | US-MYLANLABS-2016M1037769     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Injection Site Haemorrhage | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Twice                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Sep-2016                                  | 12737085                | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2016M1039187     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated; Malaise; Seizure       | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Sep-2016                                  | 12743346                | EXPEDITED (15-DAY)        |                             | HO                       | US-MYLANLABS-2016M1038053     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission           | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | Use As Directed, Prn          |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Sep-2016                                  | 12708614                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1036465     |                               |                          | Unknown             | USA                     |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------|-----------------|------------|----------------|
| Chest Discomfort; Device Failure; Feeling Abnormal; Injection Site Injury   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk                   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Sep-2016   | 12746043             | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2016429353  |                       |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Injection Site Haemorrhage  | Epipen Jr            |                    |                    | S               | Intramuscular             | 0.3 Mg, Twice         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Sep-2016   | 12726043             | EXPEDITED (15-DAY) |                    | OT              | NL-MYLANLABS-2016M1037970 |                       |                 | Unknown    | NLD            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia; Injection Site Coldness; Injection Site Pallor; Product Administered At Inappropriate Site; Vasoconstriction | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | Single Administration |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Sep-2016   | 12749648             | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2016M1039847 |                       |                 | Unknown    | FRA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen               |                    |                    | S               | Subcutaneous              | 0.3 Mg/MI, Unk        |                 | Mylan      |                |
|   | Epipen               |                    |                    | S               | Subcutaneous              | 0.3 Mg/MI, Unk        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Sep-2016   | 12749653             | EXPEDITED (15-DAY) |                    | DE              | GB-MYLANLABS-2016M1039487 |                       |                 | Unknown    | GBR            |

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| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Cardiac Arrest  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2016   | 12717793       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016415040 |                      | 22 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Chest Discomfort; Feeling Abnormal; Injection Site Injury; Product Quality Issue; Underdose   | Epipen         |                    |                    | S               | Intramuscular            | Unk                  |                 | Pfizer     |                |
|   | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2016   | 12729201       | EXPEDITED (15-DAY) |                    | OT              | NL-PFIZER INC-2016425566 |                      | 79 YR           | Female     | NLD            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Hypoaesthesia; Injection Site Coldness; Injection Site Pallor; Product Administered At Inappropriate Site; Vasoconstriction; Wrong Technique In Product Usage Process | Epipen         |                    |                    | S               | Subcutaneous             | 0.3 MI, Single       |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2016   | 12761708       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016438077 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Nausea  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2016   | 12762531       | EXPEDITED (15-DAY) |                    | DE, OT          | GB-PFIZER INC-           |                      | 11 YR           | Male       | GBR            |



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2016437505

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Cardiac Arrest; Drug Ineffective  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2016   | 12764304             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016437440  |                      | 38 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Hypoaesthesia; Intentional Product Misuse | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2016   | 12764337             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016438078  |                      | 50 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pain                                       | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2016   | 12764569             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1039529 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |

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| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 21-Sep-2016   | 12769100                 | EXPEDITED (15-DAY)        |                             | OT                       | DK-MYLANLABS-2016M1039736     |                               |                          | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Administration Site Pain          | Epipen                   |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Sep-2016   | 12769102                 | EXPEDITED (15-DAY)        |                             | LT                       | DK-MYLANLABS-2016M1039488     |                               |                          | Unknown             | DNK                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen                   |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Sep-2016   | 12773352                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1039744     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                 | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Sep-2016   | 12236297                 | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2016191897      |                               | 58 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Lip Swelling; Urticaria; Wrong Technique In Product Usage Process | Epipen                   |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
|   | Cortisone                |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
|   | Benadryl                 |                           |                             | S                        |                               | Unk                           |                          |                     |                         |
|   | Prednisone               |                           |                             | S                        |                               | Unk                           |                          |                     |                         |
|   | Zantac                   |                           |                             | S                        |                               | Unk                           |                          |                     |                         |

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| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 26-Sep-2016  | 12563097             | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2016M1029368 |                      |                 | Unknown    | FRA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue                         | Epipen Auto-Injector |                    |                    | S               |                           | 0.15 Mg, Unk         |                 | Mylan      |                |
|  | Aerius /01009701/    |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|  | Solupred /00016201/  |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Sep-2016  | 12780331             | EXPEDITED (15-DAY) |                    | OT              | DK-PFIZER INC-2016438603  |                      |                 | Female     | DNK            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Sep-2016  | 12781427             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016448890  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Intentional Product Misuse; Palpitations    | Epipen               |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Sep-2016  | 12784177             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016448889  |                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Tachycardia | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |

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| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 30-Sep-2016  | 12687761                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2016397900      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Fatigue  | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Oct-2016  | 12693869                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2016399459      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Pain In Extremity  | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Oct-2016  | 12707261                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2016412683      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Dizziness; Expired Product Administered; Injection Site Haemorrhage; Injection Site Pain | Epipen Jr               |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Oct-2016  | 12718023                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2016416658      |                               | 19 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Oct-2016  | 12790036                | EXPEDITED (15-DAY)        |                             | HO                       | US-MYLANLABS-2016M1040762     |                               |                          | Unknown             | USA                     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------|-----------------|------------|----------------|
| Device Failure   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn              |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Oct-2016  | 12823676                 | EXPEDITED (15-DAY) |                    | OT              | NL-MYLANLABS-2016M1042489 |                          |                 | Unknown    | NLD            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen                   |                    |                    | S               |                           |                          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Oct-2016  | 12824238                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016194638  |                          | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Feeling Jittery; Palpitations                  | Epipen Jr                |                    |                    | S               | Intramuscular             | Unk, Once                |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Oct-2016  | 12825754                 | DIRECT             |                    |                 |                           |                          | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Dispensing Error  | Epipen Jr                |                    |                    | S               |                           | Quantity:2 Injection(S); |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2016  | 12838627                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1042836 |                          |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; No Adverse Event | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2016  | 12838633             | EXPEDITED (15-DAY) |                    | OT              | CZ-MYLANLABS-2016M1043803 |                      |                 | Unknown    | CZE            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen               |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2016  | 12841563             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1043064 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Oct-2016  | 12844739             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016477859  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered   | Epipen Jr            |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Oct-2016  | 12844867             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1043046 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Wrong Technique In Product Usage Process | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-----------------------------|--------------------|--------------------|-----------------|--|--------------------------------------|-----------------|------------|----------------|
| 14-Oct-2016  | 12847631                    | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016479656                       |                                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Discolouration; Injection Site Pain            | Epipen Jr                   |                    |                    | S               |  | Unk                                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Oct-2016  | 12849520                    | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016479657                       |                                      | 81 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Wrong Technique In Product Usage Process | Epipen                      |                    |                    | S               | Intramuscular                                  | 0.3 Mg, Once                         |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Oct-2016  | 12860481                    | EXPEDITED (15-DAY) |                    | DE              | CA-PAR PHARMACEUTICAL COMPANIES-2016SCPR015998 |                                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Drug Dose Omission; Product Label Issue; Product Selection Error                       | Adrenalin<br>Epipen Trainer |                    |                    | S<br>S          | Unknown<br>Unknown                             | Unk Unk, Unknown<br>Unk Unk, Unknown |                 | Par        |                |
| <u>FDA Received Date</u>   | <u>Case #</u>               | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                           | <u>503B Facility</u>                 | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Oct-2016  | 12866948                    | NON-EXPEDITED      |                    |                 | US-JAZZ-2016-US-014355                         |                                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>              | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                   | <u>Dosage Text</u>                   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                  |                                    |   |      |                  |      |
|------------------|------------------------------------|---|------|------------------|------|
| Drug Interaction | Xyrem                              | S | Oral | 2.25 G, Bid      | Jazz |
|                  | Xyrem                              | S | Oral | Dose Adjustments | Jazz |
|                  | Xyrem                              | S | Oral | 4.5 G, Bid       | Jazz |
|                  | Lisinopril And Hydrochlorothiazide | S |      | Unknown Dose     |      |
|                  | Lisinopril And Hydrochlorothiazide | S |      | Unknown Dose     |      |
|                  | Epipen                             | S |      | Unknown Dose     |      |
|                  | Hydrochlorothiazide                | C |      |                  |      |
|                  | Cymbalta                           | C |      |                  |      |
|                  | Levothyroxine                      | C |      |                  |      |
|                  | Metformin Hcl                      | C |      |                  |      |
|                  | Neurontin                          | C |      |                  |      |
|                  | Ritalin                            | C |      |                  |      |
|                  | Advair                             | C |      |                  |      |
|                  | Albuterol                          | C |      |                  |      |
|                  | Amlodipine Besylate                | C |      |                  |      |
|                  | Glyburide                          | C |      |                  |      |
|                  | Robaxin-750                        | C |      |                  |      |
|                  | Cannabis                           | C |      |                  |      |
|                  | Bupropion Hcl                      | C |      |                  |      |
|                  | Oxycodone Hcl                      | C |      |                  |      |
|                  | Simvastatin                        | C |      |                  |      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2016              | 12868881      | NON-EXPEDITED    |                    | HO, LT          | US-PFIZER INC-2016488898 |                      | 15 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective      | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 21-Oct-2016              | 12873543      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1044164 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Abdominal Discomfort;<br>Asthenia; Dyspepsia; | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Mylan      |



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|        |                     |   |                          |             |  |       |
|--------|---------------------|---|--------------------------|-------------|--|-------|
| Nausea | Pepcid /00305201/   | S |                          | Unk         |  | Mylan |
|        | Benadryl /00000402/ | S |                          | Unk         |  | Mylan |
|        | Solumedrol          | S |                          | Unk         |  | Mylan |
|        | Singulair           | C | Oral                     | 10 Mg, Qam  |  | Mylan |
|        | Clarinet /01202601/ | C | Oral                     | 5 Mg, Qpm   |  | Mylan |
|        | Advair              | C | Respiratory (inhalation) | 500 Mg, Bid |  | Mylan |

| <a href="#">FDA Received Date</a>              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 26-Oct-2016                                    | 12858536                | EXPEDITED (15-DAY)        |                             | OT                       | CA-PFIZER INC-2016484159      |                               |                          | Female              | CAN                     |
| <a href="#">Preferred Term</a>                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered; Throat Tightness | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Unknown             |                         |

| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 27-Oct-2016                                  | 12820475                | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2016464176      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Injury; Product Quality Issue | Epipen Jr               |                           |                             | S                        |                               | Unk, Once                     |                          | Pfizer              |                         |

| <a href="#">FDA Received Date</a>              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 28-Oct-2016                                    | 12861532                | NON-EXPEDITED             |                             | OT                       | CA-PFIZER INC-2016482091      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Expired Product Administered | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Unknown             |                         |
|  | Epipen                  |                           |                             | S                        |                               |                               |                          | Unknown             |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 28-Oct-2016                       | 12892425               | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2016501289      |                               | 29 YR               | Male                | USA                     |

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| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Pain; Pain In Extremity | Epipen Jr      |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2016  | 12893099       | EXPEDITED (15-DAY) |                    | DE, LT          | US-PFIZER INC-2016498920  |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Drug Ineffective   | Epipen Jr      |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2016  | 12893178       | EXPEDITED (15-DAY) |                    | OT              | CH-MYLANLABS-2016M1046477 |                      |                 | Unknown    | CHE            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Wrong Technique In Product Usage Process   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Oct-2016  | 12893432       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2016501275  |                      | 10 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Palpitations; Tremor  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Nov-2016  | 12352193       | EXPEDITED (15-DAY) |                    | OT              | ES-MYLANLABS-2016M1019565 |                      |                 | Unknown    | ESP            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                      |                    |                    |                 |                           |                      |                 |            |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Pain; Nervousness   |                      | Epipen             | S                  |                 | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Nov-2016  | 12912805             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016514192  |                      | 70 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Gait Disturbance; Injection Site Pain; Musculoskeletal Stiffness; Wrong Technique In Product Usage Process | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
|  | Epipen               |                    |                    | S               |                           |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Nov-2016  | 12913354             | EXPEDITED (15-DAY) |                    | OT              | FI-MYLANLABS-2016M1047785 |                      |                 | Unknown    | FIN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Malfunction   | Epipen Junior        |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Nov-2016  | 12921124             | EXPEDITED (15-DAY) |                    | OT              | ES-PFIZER INC-2016255398  |                      | 42 YR           | Female     | ESP            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Nervousness   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Nov-2016  | 12838648             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1037603 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission   | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |

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| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------------|-----------------|------------|----------------|
| 15-Nov-2016   | 12945722             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1048170 |                                 |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission                    | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn                     |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Nov-2016   | 12945728             | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2016M1048471 |                                 |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               |                           | Unk, Prn                        |                 | Mylan      |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Nov-2016   | 12592642             | NON-EXPEDITED      |                    |                 | PHEH2016US018077          |                                 | 17 YR           | Male       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Product Use In Unapproved Indication; Rash; Urticaria | Zofran Injection     |                    |                    | S               | Unknown                   | Unk                             |                 | Novartis   |                |
|   | Epipen               |                    |                    | S               | Unknown                   | Unk                             |                 |            |                |
|   | Advair               |                    |                    | C               | Unknown                   | Unk                             |                 |            |                |
| <u>FDA Received Date</u>                              | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>            | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Nov-2016   | 12908438             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2015358374  |                                 | 78 YR           | Male       | USA            |
| <u>Preferred Term</u>                                 | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>              | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity; Iodine Allergy                 | Epipen               |                    |                    | S               |                           | 0.3 G, Unk (Auto Injector 0.3g) |                 | Pfizer     |                |
|   | Iodine               |                    |                    | S               | Oral                      | Unk                             |                 |            |                |

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| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 18-Nov-2016  | 12957569                | EXPEDITED (15-DAY)        |                             | LT                       | ZA-MYLANLABS-2016M1050116     |                               |                          | Unknown             | ZAF                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Jr               |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Nov-2016  | 12965510                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1049605     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Nov-2016  | 12937184                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2016525485      |                               | 16 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Anxiety; Feeling Jittery; Heart Rate Increased; Injection Site Haemorrhage; Palpitations | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Nov-2016  | 12969083                | DIRECT                    | Y                           | OT                       |                               |                               | 6 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Aggression; Device Malfunction; Injection Site Erosion; Injection Site Laceration; Patient Uncooperative                 | Epi Pen Jr              |                           |                             | S                        |                               |                               |                          | Meridian            |                         |

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| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 29-Nov-2016                             | 12835857             | EXPEDITED (15-DAY) |                    | HO, OT          | JP-PFIZER INC-2016464855  |   | 79 YR           | Female     | JPN            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock;<br>Asthenia; Tremor | Epipen 0.3mg         |                    |                    | S               | Subcutaneous              | 0.3 Mg, Single  |                 | Pfizer     |                |
|   | Lyrica               |                    |                    | C               |                           | 125 Mg, Daily 50 Mg In<br>The Morning And 75 Mg In<br>The Evening |                 |            |                |
|   | Opalmon              |                    |                    | C               | Oral                      | 5 Ug, 3x/Day  |                 |            |                |
|   | Mecobalamin          |                    |                    | C               | Oral                      | 1 Df, 3x/Day  |                 |            |                |
|   | Mucosta              |                    |                    | C               |                           | 100 Mg, 3x/Day  |                 |            |                |
|   | Alinamin F           |                    |                    | C               | Oral                      | 50 Mg, 2x/Day   |                 |            |                |
|   | Edirol               |                    |                    | C               |                           | 0.75 Ug, 1x/Day   |                 |            |                |
|   | Myslee               |                    |                    | C               |                           | 5 Mg, 1x/Day Before<br>Bedtime                                    |                 |            |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Nov-2016                             | 12982218             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016544898  |   |                 | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Tremor                                  | Epipen               |                    |                    | S               |                           | Unk, Prn  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Dec-2016                             | 12911496             | EXPEDITED (15-DAY) |                    | OT              | BE-MYLANLABS-2016M1047666 |   |                 | Unknown    | BEL            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                          | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | 0.3 Mg, Unk   |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Dec-2016                             | 12937133             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1048923 |   |                 | Unknown    | USA            |

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| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|------------------------|-----------------|------------|----------------|
| Injection Site Laceration  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Once          |                 | Mylan      |                |
|  | Epipen Jr. Auto-Injector |                    |                    | S               |                           |                        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Dec-2016  | 12990575                 | EXPEDITED (15-DAY) |                    | OT              | AT-MYLANLABS-2016M1052608 |                        |                 | Unknown    | AUT            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Malfunction                               | Epipen                   |                    |                    | S               |                           | Unk                    |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Dec-2016  | 12982197                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2016544899  |                        | 8 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Bruising | Epipen                   |                    |                    | S               |                           | Unk                    |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Dec-2016  | 12947439                 | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016530429  |                        | 6 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Needle Issue                          | Epipen Jr                |                    |                    | S               | Intramuscular             | 0.15 Mg, Once          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Dec-2016  | 12980484                 | EXPEDITED (15-DAY) |                    | HO, OT          | JP-MYLANLABS-2016M1043893 |                        |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock; Asthenia; Tremor                             | Epipen                   |                    |                    | S               | Subcutaneous              | 0.3 Mg, Total          |                 | Mylan      |                |
|  | Lyrica                   |                    |                    | C               |                           | 125 Mg, Daily 50 Mg In | Mylan           |            |                |

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|                       |   |      |  |  |   |       |
|-----------------------|---|------|--|--|---|-------|
|                       |   |      |  |  | The Morning And 75 Mg In<br>The Evening |       |
| Opalmon               | C | Oral |  |  | 5 Mg, Tid                               | Mylan |
| Mecobalamin           | C | Oral |  |  | 1 Df, Tid                               | Mylan |
| Mucosta               | C |      |  |  | 100 Mg, Tid                             | Mylan |
| Alinamin F /00257801/ | C | Oral |  |  | 50 Mg, Bid                              | Mylan |
| Edirol                | C |      |  |  | 0.75 Mg, Qd                             | Mylan |
| Myslee                | C |      |  |  | 5 Mg, Qd Before Bedtime                 | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 08-Dec-2016              | 13009041      | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-<br>2016560919 |                      |            | Unknown    | JPN            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Autism Spectrum Disorder | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2016              | 12953137      | EXPEDITED (15-DAY) |                    | OT              | FI-MYLANLABS-<br>2016M1046458 |                      |            | Unknown    | FIN            |

| <u>Preferred Term</u>                 | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>                              | <u>Duration</u> | <u>Mfr</u> |
|---------------------------------------|----------------|--------------|------------|-------------|--------------|---|-----------------|------------|
| Device Failure; Device<br>Malfunction | Epipen Jr      |              |            | S           |              | Daily Dose: 0.15 Mg<br>Milligram(S) Every Total |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|------------|------------|----------------|
| 09-Dec-2016              | 13014498      | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-<br>2016M1054578 |                      |            | Unknown    | JPN            |

| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--------------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Autism Spectrum Disorder | Epipen         |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|------------------------------|----------------------|------------|------------|----------------|
| 12-Dec-2016              | 13017235      | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-<br>2016570497 |                      |            | Female     | USA            |



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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Completed Suicide   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Dec-2016   | 13009050             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016564476  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Injury; Skeletal Injury              | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Dec-2016   | 13026636             | EXPEDITED (15-DAY) |                    | OT              | SE-PFIZER INC-2016575660  |                      | 5 YR            | Male       | SWE            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Injury                      | Epipen               |                    |                    | S               | Intramuscular             | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Dec-2016   | 13035112             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016582337  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Loss Of Consciousness   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Dec-2016   | 13036503             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2016M1053880 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Incomplete; Hypoaesthesia; Injection Site Pain; Injection Site Swelling | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                          |                           |                             |                          |                               |                               |                             |                          |                         |  |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|--|
| Epipen Auto-Injector  |                          |                           | S                           |                          | Intramuscular                 |                               | 0.3 Mg, Once                |                          | Mylan                   |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 19-Dec-2016   | 13042683                 | NON-EXPEDITED             |                             | LT, OT                   | US-PFIZER INC-2016586505      |                               | 19 YR                       | Female                   | USA                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Drug Effect Incomplete; Hypoaesthesia; Injection Site Pain; Injection Site Swelling | Epipen Jr                |                           |                             |                          | S                             | Intramuscular                 | 0.3 Mg                      |                          | Pfizer                  |  |
|   |                          |                           |                             |                          |                               |                               |                             |                          |                         |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 21-Dec-2016   | 13051606                 | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2016586504      |                               | 5 YR                        | Male                     | USA                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Injection Site Laceration   | Epipen Jr                |                           |                             |                          | S                             | Intramuscular                 | 0.15 Mg, Prn                |                          | Pfizer                  |  |
|   | Diphenhydramine Hcl      |                           |                             |                          | S                             |                               | Unk                         |                          | Unknown                 |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 22-Dec-2016   | 13008569                 | NON-EXPEDITED             |                             | DE, HO, LT, OT           | US-PFIZER INC-2016560625      |                               | 11 YR                       | Male                     | USA                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Drug Ineffective  | Epipen                   |                           |                             |                          | S                             |                               | Unk Unk, Once               |                          | Pfizer                  |  |
|   | Epipen                   |                           |                             |                          | S                             |                               | Unk, Once                   |                          | Pfizer                  |  |
|   | Epipen                   |                           |                             |                          | S                             |                               | Unk, Once                   |                          | Pfizer                  |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 22-Dec-2016   | 13055501                 | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1055614     |                               |                             | Unknown                  | USA                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Drug Effect Incomplete  | Epipen Jr. Auto-Injector |                           |                             |                          | S                             |                               | Unk Unk, Once               |                          | Mylan                   |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                |                    |                    |                 |                           |                      |                    |                 |                |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| Epipen Jr. Auto-Injector                                       |                |                    | S                  |                 | Unk, Once                 |                      |                    | Mylan           |                |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 27-Dec-2016  | 13063640       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2016596127  |                      |                    | Male            | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Effect Incomplete   | Epipen Jr      |                    |                    |                 | S                         |                      | Unk Unk, Once      |                 | Pfizer         |
|  | Epipen Jr      |                    |                    |                 | S                         |                      | Unk, Once          |                 | Pfizer         |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 27-Dec-2016  | 13066737       | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2016596130  |                      |                    | Male            | USA            |
| <u>Preferred Term</u>  | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective   | Epipen         |                    |                    |                 | S                         |                      | Unk, Once          |                 | Pfizer         |
|  | Epipen         |                    |                    |                 | S                         |                      | Unk, Once          |                 | Pfizer         |
|  | Epipen         |                    |                    |                 | S                         |                      | Unk, Once          |                 | Pfizer         |
|  | Epipen         |                    |                    |                 | S                         |                      | Unk, Once          |                 | Pfizer         |
|  | Epipen         |                    |                    |                 | S                         |                      | Unk, Once          |                 | Pfizer         |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 29-Dec-2016  | 13074137       | EXPEDITED (15-DAY) |                    | OT              | FI-MYLANLABS-2016M1058145 |                      |                    | Unknown         | FIN            |
| <u>Preferred Term</u>  | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Injection Site Injury;<br>Injection Site Scar; Needle<br>Issue | Epipen Jr      |                    |                    |                 | S                         |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>                                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 30-Dec-2016  | 13076890       | EXPEDITED (15-DAY) |                    | OT              | FI-PFIZER INC-2016602170  |                      | 4 YR               | Unknown         | FIN            |
| <u>Preferred Term</u>  | <u>Product</u> |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Injection Site Injury;<br>Injection Site Scar; Needle<br>Issue                           |                         | Epipen Jr                 |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jan-2017  | 13045982                | EXPEDITED (15-DAY)        |                             | HO                       | US-PFIZER INC-<br>2016582831  |                               | 20 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Foreign Body; Injection<br>Site Injury; Product<br>Administered At<br>Inappropriate Site | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jan-2017  | 13081052                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-<br>2016603948  |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To<br>Product; Injection Site<br>Injury; Product Quality<br>Issue    | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jan-2017  | 13085423                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-<br>2016603958  |                               | 304 DAY                  | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Bruising;<br>Injection Site Injury;<br>Product Quality Issue              | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Pfizer              |                         |
|  | Benadryl                |                           |                             | C                        | Oral                          | Unk, Prn                      |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 05-Jan-2017  | 13092883                | DIRECT                    | Y                           | OT                       |                               |                               | 8 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                      |                           |                    |                 |                               |                      |                 |            |                |
|--|----------------------|---------------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Anaphylactic Reaction;<br>Injection Site Bruising;<br>Injection Site Pain; Needle<br>Issue |                      | Epi-Pen Jr, 0.15 Mg Mylan |                    | S               | Intramuscular                 |                      | Mylan           |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Jan-2017  | 13106975             | EXPEDITED (15-DAY)        |                    | OT              | NO-MYLANLABS-<br>2017M1001642 |                      |                 | Unknown    | NOR            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device<br>Malfunction  | Epipen Auto-Injector |                           |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Jan-2017  | 13114101             | NON-EXPEDITED             |                    | HO, LT          | US-PFIZER INC-<br>2017007174  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device<br>Use Issue; Drug Dose<br>Omission                                 | Epipen               |                           |                    | S               |                               | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Jan-2017  | 13122337             | EXPEDITED (15-DAY)        |                    | OT              | SE-MYLANLABS-<br>2017M1002762 |                      |                 | Unknown    | SWE            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Expired Product<br>Administered; Fatigue                | Epipen               |                           |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>          | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Jan-2017  | 13122896             | EXPEDITED (15-DAY)        |                    | OT              | US-PFIZER INC-<br>2017007098  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>              | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle<br>Issue  | Epipen               |                           |                    | S               |                               | Unk                  |                 | Pfizer     |                |

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| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 19-Jan-2017                                  | 13130697                | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2017016200      |                               | 59 YR                    | Male                | JAM                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Expired Product Administered | Epipen 0.3mg            |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Jan-2017                                  | 13131395                | EXPEDITED (15-DAY)        |                             | HO                       | NZ-MYLANLABS-2017M1003453     |                               |                          | Unknown             | NZL                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Expired Product Administered | Epipen Auto-Injector    |                           |                             | S                        |                               | 300 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Jan-2017                                  | 13131669                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1001959     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                               | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>            | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jan-2017                                  | 13055467                | EXPEDITED (15-DAY)        |                             | HO                       | US-MYLANLABS-2016M1056100     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>               | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Stress Cardiomyopathy; Syncope               | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|  | Losartan                |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |
|  | Synthroid               |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |
|  | Probiotic /06395501/    |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |
|  | Vitamin D /00107901/    |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |
|  | Montelukast             |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---|--------------------|--------------------|-----------------|---------------------------|------------------------|-----------------|------------|----------------|
| 23-Jan-2017   | 13122753                                  | EXPEDITED (15-DAY) |                    | LT              | FR-MYLANLABS-2017M1002517 |                        |                 | Unknown    | FRA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue  | Epipen                                    |                    |                    | S               | Subcutaneous              | Unk                    |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jan-2017   | 13139997                                  | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017026499  |                        | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen                                    |                    |                    | S               | Intramuscular             | 0.3 Mg, As Needed(Prn) |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jan-2017   | 13140659                                  | EXPEDITED (15-DAY) |                    | HO              | JP-MYLANLABS-2017M1003774 |                        |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               | Intramuscular             | 0.3 Mg, Single         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jan-2017   | 13141129                                  | EXPEDITED (15-DAY) |                    | LT, OT          | US-PFIZER INC-2017026500  |                        | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Injection Site Pain; Injection Site Warmth; Injury Associated With Device; Vomiting | Epipen                                    |                    |                    | S               | Intramuscular             | 0.3 Mg, Once           |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Jan-2017   | 13144066                                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017028215  |                        | 8 YR            | Male       | USA            |

# FDA Adverse Event Reporting System

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### Detailed Report

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Issue; Injection Site Pain; Injury Associated With Device                                      | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Jan-2017   | 13145366                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1003029     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Injection Site Pain; Injection Site Warmth; Injury Associated With Device; Vomiting | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Jan-2017   | 13145592                | EXPEDITED (15-DAY)        |                             | HO                       | NZ-PFIZER INC-2017031486      |                               | 13 YR                    | Male                | NZL                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Expired Product Administered  | Epipen                  |                           |                             | S                        |                               | 300 Mg, Prn                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Jan-2017   | 13145673                | EXPEDITED (15-DAY)        |                             | OT                       | BE-PFIZER INC-2016515921      |                               | 57 YR                    | Female              | BEL                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Issue; Incorrect Route Of Drug Administration                                  | Epipen                  |                           |                             | S                        | Subcutaneous                  | 0.3 Mg, Unk                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-Jan-2017   | 13068670                | EXPEDITED (15-DAY)        |                             | HO                       | US-PFIZER INC-2016596131      |                               | 75 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



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|                                   |             |   |               |             |        |
|-----------------------------------|-------------|---|---------------|-------------|--------|
| Stress Cardiomyopathy;<br>Syncope | Epipen      | S | Intramuscular | 0.3 Mg, Prn | Pfizer |
|                                   | Losartan    | C |               | Unk         |        |
|                                   | Synthroid   | C |               | Unk         |        |
|                                   | Probiotic   | C |               | Unk         |        |
|                                   | Vitamin D   | C |               | Unk         |        |
|                                   | Montelukast | C |               | Unk         |        |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 26-Jan-2017                       | 13154099               | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1003013     |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure                 | Epipen Auto-Injector    |                       |                     | S                    | Intramuscular         | 0.3 Mg, Once                |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Jan-2017                       | 13089358               | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2016605435      |                               |                     | Female              | USA                     |

| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure; Device Use Issue; Expired Product Administered | Epipen                  |                       |                     | S                    |                       | Unk                         |                          | Pfizer              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Jan-2017                       | 13131308               | EXPEDITED (15-DAY)        |                             | OT                       | CA-PFIZER INC-2017007195      |                               |                     | Female              | CAN                     |

| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|----------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Drug Dose Omission; Needle Issue | Epipen                  |                       |                     | S                    |                       | Unk                         |                          | Pfizer              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 27-Jan-2017                       | 13159596               | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2017038434      |                               | 55 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |   |                    |                    |                 |                           |                      |                 |            |                |
|--|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Needle Issue   | Epipen                                    |                    | S                  | Intramuscular   | 0.3 Mg, Once              |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jan-2017  | 13076807                                  | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2016M1059161 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered   | Epipen                                    |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jan-2017  | 13076810                                  | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2016M1059162 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Incomplete; Expired Product Administered                                   | Epipen                                    |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jan-2017  | 13164710                                  | EXPEDITED (15-DAY) |                    | LT              | AU-MYLANLABS-2017M1004943 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Jan-2017  | 13167762                                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017038433  |                      | 64 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Expired Product Administered; Feeling Jittery | Epipen                                    |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>  | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
|---|--|--------------------|--------------------|--------------------------------------|---|----------------------------|-----------------|-----------------|----------------|
| 06-Feb-2017   | 13066730   | NON-EXPEDITED      |                    | LT, OT                               | US-PFIZER INC-2016596128  |                            |                 | Unknown         | USA            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>      |                |
| Drug Ineffective;<br>Intentional Product<br>Misuse; Liquid Product<br>Physical Issue  | Epipen   |                    |                    | S                                    |   | Unk                        |                 | Pfizer          |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>  | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 06-Feb-2017   | 13143405   | EXPEDITED (15-DAY) |                    | OT                                   | US-PFIZER INC-2017028162  |                            | 27 YR           | Female          | USA            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>      |                |
| Accidental Exposure To<br>Product; Device Defective;<br>Expired Product<br>Administered; Injury<br>Associated With Device;<br>Skeletal Injury | Epipen Jr<br>Sertraline<br>Venlafaxine   |                    |                    | S<br>C<br>C                          |   | 100 Mg, Unk<br>75 Mg, Unk  |                 | Pfizer          |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>                      | <u>Mfr Control #</u>  | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 07-Feb-2017   | 13191611   | EXPEDITED (15-DAY) |                    | HO                                   | CA-BAUSCH-BL-2017-002648  |                            | 52 YR           | Male            | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>                          | <u>Route</u>  | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u>      |                |
| Hypersensitivity  | Besivance (Besifloxacin<br>Ophthalmic Suspension) 0.6%<br>Amlodipine<br>Betoptic S Oph Sus 0.25%<br>Cialis<br>Epipen<br>Nasonex<br>Olopatadine<br>Ratio-Prednisolone |                    |                    | S<br>S<br>S<br>S<br>S<br>S<br>S<br>S | Unknown<br>Oral<br>Unknown<br>Unknown<br>Intramuscular<br>Ophthalmic<br>Unknown | As Required<br>As Required |                 | Bausch And Lomb |                |

# FDA Adverse Event Reporting System

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### Detailed Report

|                    |   |         |
|--------------------|---|---------|
| Ratio-Prednisolone | S | Unknown |
| Ratio-Prednisolone | S | Unknown |
| Teva-Prednisone    | S | Unknown |
| Vigamox            | S | Unknown |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 07-Feb-2017              | 13192221      | DIRECT           | Y                  |                 |                      |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                                  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Needle Issue; Wrong Technique In Product Usage Process | Epipen         |              |            | S           |              |                    |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-Feb-2017              | 13205637      | EXPEDITED (15-DAY) |                    | OT              | IE-PFIZER INC-2017059719 |                      |            | Female     | IRL            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Injection Site Discolouration; Injection Site Hypoaesthesia | Epipen 0.3mg   |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Feb-2017              | 12083605      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1040987 |                      | 69 YR      | Female     | USA            |

| <u>Preferred Term</u>                         | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; Injury Associated With Device | Epipen Auto-Injector |              |            | S           | Unknown      | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 16-Feb-2017              | 12083607      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2015M1044913 |                      | 9 YR       | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product By Child; Heart Rate Increased                            |                         | Epipen Auto-Injector      |                             | S                        |                               | 0.3 Unk, Unk                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13007216                | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2016M1053620     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Haemorrhage | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13241279                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1001790     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        |                               | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13241284                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2015M1046828     |                               | 18 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13241287                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1000002     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

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| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Feb-2017  | 13241290                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1003569 |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241292                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1002597 |                      | 81 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device                                | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241295                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1001620 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                               | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241297                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1001286 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion  | Epipen Trainer           |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241305                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1002837 |                      | 21 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|  |                          |                    |                    |                 |                           |                      |                 |            |                |

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|  |                      |                  |                    |                 |                           |                    |                      |                 |            |                |
|--|----------------------|------------------|--------------------|-----------------|---------------------------|--------------------|----------------------|-----------------|------------|----------------|
| Device Failure   | Epipen Auto-Injector |                  | S                  |                 | Intramuscular             |                    | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241306             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1004650 |                    |                      | 72 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pallor        | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Once       |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241309             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1008167 |                    |                      | 57 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn        |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241311             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1000259 |                    |                      | 44 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Unevaluable Event            | Epipen Auto-Injector |                  |                    | S               | Unknown                   | Unk                |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      |                    | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241312             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1002010 |                    |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u> |                      | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered | Epipen Auto-Injector |                  |                    | S               |                           | Unk                |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Feb-2017   | 13241316                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1006383 |                      | 4 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising;<br>Injection Site Pain; Injury<br>Associated With Device | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241320                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1007299 |                      | 60 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241325                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1010134 |                      | 2 YR            | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241330                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1008396 |                      | 20 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241331                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1012459 |                      | 26 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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| Accidental Exposure To Product; Device Failure; Injection Site Bruising  | Epipen Auto-Injector    | S                         | Intramuscular               | 0.3 Mg, Once             |                               |                               |                          | Mylan               |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
|  | Epipen Auto-Injector    | S                         |                             |                          |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13241336                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1013063     |                               | 39 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Feeling Jittery; Heart Rate Increased; Injection Site Bruising; Injection Site Haemorrhage; Product Administered At Inappropriate Site | Epipen Auto-Injector    |                           |                             | S                        |                               | 0.3 Mg, Unk                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13241340                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1008896     |                               | 48 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Injection Site Haemorrhage   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13241341                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1011929     |                               | 70 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Expired Product Administered   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017  | 13241370                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1013916     |                               | 49 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|   |                          |                      |                    |                 |                           |                      |                 |            |                |
|---|--------------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Expired Product Administered; Feeling Jittery |                          | Epipen Auto-Injector | S                  | Intramuscular   | 0.3 Mg, Once              |                      | Mylan           |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241376                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1016326 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                      |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|   | Epipen Auto-Injector     |                      |                    | S               |                           |                      |                 | Mylan      |                |
|   | Epipen Auto-Injector     |                      |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241385                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1020450 |                      | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Bruising       | Epipen Auto-Injector     |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241388                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1013918 |                      | 69 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                      |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241390                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1016722 |                      | 10 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Jr. Auto-Injector |                      |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
|   | Epipen Jr. Auto-Injector |                      |                    | S               |                           |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>                            | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|-----------------------|-----------------|------------|----------------|
| 16-Feb-2017   | 13241391                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1018462 |                       | 6 YR            | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Epistaxis           | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                   |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241403                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1019248 |                       | 65 YR           | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                      | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn If Needed |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241413                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1018687 |                       |                 | Unknown    | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased; Expired Product Administered | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Once          |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241451                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1021150 |                       |                 | Unknown    | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With Device                       | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                   |                 | Mylan      |                |
| <u>FDA Received Date</u>                            | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241455                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1023051 |                       | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>                               | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |

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|   |                          |                  |                    |                 |                           |                      |                 |            |                |
|---|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector     | S                | Intramuscular      | 0.3 Mg, Once    |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241468                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1026501 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product                                | Epipen Jr. Auto-Injector |                  |                    | S               |                           | 0.15 Mg, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241469                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1024488 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     | S                |                    |                 |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241471                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1025269 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising                                       | Epipen Jr. Auto-Injector | S                | Intramuscular      |                 |                           | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241473                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1024641 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injury Associated With Device | Epipen Auto-Injector     | S                |                    |                 |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241480                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1027532 |                      | 27 YR           | Male       | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241491             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1029564 |                      | 44 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; No Adverse Event  | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241493             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1032881 |                      | 63 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pain; Wrong Technique In Product Usage Process | Epipen Auto-Injector |                  |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241494             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1028387 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241495             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1030316 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                         |                           |                             |                          |                               |                               |                          |                     |                         |  |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|--|
| Drug Prescribing Error; No Adverse Event   |                         | Epipen Auto-Injector      |                             | S                        | Intramuscular                 |                               | 0.3 Mg, Prn              |                     | Mylan                   |  |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 16-Feb-2017  | 13241499                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1024041     |                               | 65 YR                    | Female              | USA                     |  |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |  |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Bruising; Injection Site Coldness; Injection Site Hypoaesthesia; Injection Site Injury; Injection Site Pain; Injection Site Swelling; Pain In Extremity; Palpitations | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |  |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 16-Feb-2017  | 13241500                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1027803     |                               |                          | Male                | USA                     |  |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |  |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        |                               | 0.3 Unk, Unk                  |                          | Mylan               |                         |  |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 16-Feb-2017  | 13241552                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1053558     |                               | 49 YR                    | Female              | USA                     |  |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |  |
| Accidental Exposure To Product   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |  |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 16-Feb-2017  | 13241554                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1035905     |                               |                          | Female              | USA                     |  |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |  |

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|   |                          |                      |                    |                 |                           |                      |                 |            |                |
|---|--------------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Screen False Positive  |                          | Epipen Auto-Injector |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241556                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1034204 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Laceration | Epipen Auto-Injector     |                      |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241558                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1012858 |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Feeling Jittery; Palpitations                           | Epipen Auto-Injector     |                      |                    | S               | Intramuscular             | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241561                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1039014 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child   | Epipen Jr. Auto-Injector |                      |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13241564                 | NON-EXPEDITED        |                    |                 | US-MYLANLABS-2016M1043067 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; No Adverse Event          | Epipen Jr. Auto-Injector |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Feb-2017                             | 13241565                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1036181     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Incorrect Dose Administered             | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017                             | 13241568                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1016898     |                               | 69 YR                    | Unknown             | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                          | Epipen Auto-Injector     |                           |                             | S                        | Unknown                       | Unk, Prn                      |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017                             | 13241578                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1040702     |                               | 2 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017                             | 13241583                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1051410     |                               | 55 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission      | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>       | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2017                             | 13241585                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2016M1039685     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>          | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                          |                    |                    |                 |                           |                      |                 |            |                |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product   | Epipen Auto-Injector     |                    | S                  | Intramuscular   | 0.3 Mg, Prn               |                      | Mylan           |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241587                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1046495 |                      | 70 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Gait Disturbance; Injection Site Pain; Musculoskeletal Stiffness; Wrong Technique In Product Usage Process | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|  | Epipen Auto-Injector     |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241590                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1049991 |                      | 67 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241591                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1036456 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241592                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1054753 |                      | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Feb-2017  | 13241596                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1044445 |                      | 26 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241598                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1044624 |                      | 10 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Palpitations; Tremor  | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241600                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1031484 |                      | 3 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Psychomotor Hyperactivity   | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241603                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1047823 |                      | 16 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Feeling Jittery; Heart Rate Increased; Injection Site Haemorrhage; Palpitations | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Feb-2017  | 13241605                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1038045 |                      | 69 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241607                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1024092 |                      | 5 YR            | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Heart Rate Increased; Injury Associated With Device; Oxygen Saturation Decreased | Epipen Auto-Injector     |                  |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241609                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1038239 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Expired Product Administered   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241614                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1037941 |                      | 10 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Intercepted Drug Prescribing Error; No Adverse Event   | Epipen Jr. Auto-Injector |                  |                    | S               |                           | 0.15 Mg, Unk         |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Feb-2017  | 13241615             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1048941 |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241617             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1039129 |                      | 48 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241624             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1036108 |                      | 82 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241627             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1043461 |                      | 28 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered; Maternal Exposure During Pregnancy | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241637             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1045529 |                      | 29 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|  |                      |                  |                    |                 |                           |                      |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |                  |                      |                 |                           |                      |                    |                 |                |  |
|--|--------------------------|------------------|----------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|--|
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Pain; Pain In Extremity |                          |                  | Epipen Auto-Injector |                 | S                         | Intramuscular        | 0.3 Mg, Unk        |                 | Mylan          |  |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u>   | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |  |
| 16-Feb-2017  | 13241648                 | NON-EXPEDITED    |                      |                 | US-MYLANLABS-2016M1041465 |                      | 8 YR               | Male            | USA            |  |
| <u>Preferred Term</u>  | <u>Product</u>           |                  | <u>Comp.</u>         | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |  |
| Accidental Exposure To Product By Child  | Epipen Jr. Auto-Injector |                  |                      |                 | S                         |                      | 0.15 Mg, Once      |                 | Mylan          |  |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u>   | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |  |
| 16-Feb-2017  | 13241651                 | NON-EXPEDITED    |                      |                 | US-MYLANLABS-2016M1043431 |                      |                    | Female          | USA            |  |
| <u>Preferred Term</u>  | <u>Product</u>           |                  | <u>Comp.</u>         | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |  |
| Accidental Exposure To Product   | Epipen Auto-Injector     |                  |                      |                 | S                         | Intramuscular        | Unk                |                 | Mylan          |  |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u>   | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |  |
| 16-Feb-2017  | 13241657                 | NON-EXPEDITED    |                      |                 | US-MYLANLABS-2016M1043071 |                      | 3 YR               | Male            | USA            |  |
| <u>Preferred Term</u>  | <u>Product</u>           |                  | <u>Comp.</u>         | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |  |
| Accidental Exposure To Product By Child; Injection Site Discolouration; Injection Site Pain          | Epipen Jr. Auto-Injector |                  |                      |                 | S                         |                      | Unk                |                 | Mylan          |  |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u>   | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |  |
| 16-Feb-2017  | 13241663                 | NON-EXPEDITED    |                      |                 | US-MYLANLABS-2016M1038187 |                      | 38 YR              | Male            | USA            |  |
| <u>Preferred Term</u>  | <u>Product</u>           |                  | <u>Comp.</u>         | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |  |
| Accidental Exposure To Product; Injection Site   | Epipen Auto-Injector     |                  |                      |                 | S                         | Intramuscular        | 0.3 Mg, Prn        |                 | Mylan          |  |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Hypoaesthesia; Intentional  
Product Misuse

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Feb-2017                       | 13241688                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-<br>2016M1043841 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Off Label Use                     | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk Mg, Unk                   |                          | Mylan               |                         |

| <a href="#">FDA Received Date</a>     | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Feb-2017                           | 13241693                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-<br>2016M1050194 |                               | 8 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>        | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose<br>Omission | Epipen Auto-Injector    |                           |                             | S                        |                               | 0.3 Mg, Prn                   |                          | Mylan               |                         |

| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Feb-2017   | 13241695                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-<br>2016M1043068 |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To<br>Product; Expired Product<br>Administered; No Adverse<br>Event | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Feb-2017                       | 13241697                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-<br>2016M1041663 |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                    | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 16-Feb-2017                       | 13241702               | NON-EXPEDITED             |                             |                          | US-MYLANLABS-<br>2016M1032658 |                               | 77 YR               | Female              | USA                     |

# FDA Adverse Event Reporting System

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| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241705                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1043069 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; No Adverse Event | Epipen Jr. Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241708                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1050570 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Tremor   | Epipen Auto-Injector     |                  |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13241729                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1039919 |                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Tachycardia                           | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13242056                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1036096 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Product Misuse; No Adverse Event                                   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

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| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Feb-2017                             | 13242059             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1037950 |                      | 74 YR           | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                          | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017                             | 13242060             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1045443 |                      | 53 YR           | Male       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                          | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017                             | 13242069             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1043465 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                          | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017                             | 13242071             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2016M1043607 |                      | 13 YR           | Male       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017                             | 13242074             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2016M1043234 |                      | 7 YR            | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event; Off Label Use         | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Feb-2017   | 13242076             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1052429 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered                                      | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen Auto-Injector |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13242077             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1034403 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13242078             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1039116 |                      | 50 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Pain | Epipen Auto-Injector |                  |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13242080             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1033433 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pain  | Epipen Trainer       |                  |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017   | 13242082             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2016M1057242 |                      | 305 DAY         | Female     | USA            |

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| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|--------------------------|------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Injection Site Bruising;<br>Injury Associated With<br>Device | Epipen Jr. Auto-Injector |                  |                    | S               | Intramuscular                 | 0.15 Mg, Prn         |                 | Mylan      |                |
|  | Benadryl /00000402/      |                  |                    | C               | Oral                          | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13242108                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2016M1035672 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular                 | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13242114                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2016M1033219 |                      | 64 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                  |                    | S               | Intramuscular                 | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13242122                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2016M1034171 |                      | 41 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                  |                    | S               | Subcutaneous                  | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>            | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Feb-2017  | 13242132                 | NON-EXPEDITED    |                    |                 | US-MYLANLABS-<br>2016M1034428 |                      | 19 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose<br>Omission                        | Epipen Auto-Injector     |                  |                    | S               | Intramuscular                 | 0.3 Mg, Unk          |                 | Mylan      |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 21-Feb-2017   | 12723898                           | EXPEDITED (15-DAY) |                    | DE              | GB-MYLANLABS-2016M1038107 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Allergy To Arthropod Sting; Device Breakage; Device Failure; Device Malfunction; Dyspnoea                       | Epipen                             |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Feb-2017   | 13256482                           | DIRECT             | Y                  | HO, RI          |                           |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction  | Epinephrine (Epipen Auto-Injector) |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Feb-2017   | 13264082                           | DIRECT             | Y                  | HO, LT, OT      |                           |                      | 17 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury; Vascular Pseudoaneurysm   | Epipen                             |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Feb-2017   | 13235496                           | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2017060587  |                      | 55 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dyspnoea; Hypotension; Oxygen Saturation Decreased; Pharyngeal Oedema; Wrong Technique In Product Usage Process | Epipen                             |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 23-Feb-2017   | 13264351                                  | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017072010  |                      | 53 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Needle Issue; Product Quality Issue                                  | Epipen                                    |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Feb-2017   | 13269103                                  | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-2014165887  |                      | 10 YR           | Male       | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Haemorrhage Subcutaneous; Injection Site Bruising; Injection Site Discolouration | Epipen 0.15mg                             |                    |                    | S               | Subcutaneous              | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Feb-2017   | 13274772                                  | EXPEDITED (15-DAY) |                    | OT              | ZA-MYLANLABS-2017M1009369 |                      |                 | Unknown    | ZAF            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Product Quality Issue   | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Feb-2017   | 13241288                                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017070820  |                      | 19 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity   | Epipen                                    |                    |                    | S               |                           | Unk                  |                 | Unknown    |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 01-Mar-2017   | 13285078                                  | EXPEDITED (15-DAY) |                    | OT              | ZA-MYLANLABS-2017M1009376 |                      |                 | Unknown    | ZAF            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Issue; Needle Issue  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Mar-2017   | 13288274                                  | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1012024 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Product Use Issue   | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Epipen Auto-Injector                      |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Mar-2017   | 13297631                                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017091652  |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Skeletal Injury; Wrong Technique In Product Usage Process | Epipen                                    |                    |                    | S               |                           | Unk                  |                 | Unknown    |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Mar-2017   | 13307800                                  | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2017M1013427 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Peripheral Swelling   | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Mar-2017   | 13288366                                  | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2017M1012556 |                      |                 | Unknown    | AUS            |

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| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective; Injection Site Pain; Product Quality Issue   | Epipen         |                    |                    | S               | Intramuscular            |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Mar-2017  | 13321590       | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2017103994 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Joint Swelling; Peripheral Swelling  | Epipen         |                    |                    | S               | Intramuscular            | 0.3 Mg, Unk          |                 | Pfizer     |                |
|  | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Mar-2017  | 13299814       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017094172 |                      | 10 YR           | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Movement Impairment; Injection Site Nerve Damage; Injection Site Pain; Injection Site Pallor; Injection Site Reaction | Epipen         |                    |                    | S               |                          | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Mar-2017  | 13329808       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017105896 |                      | 71 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Feeling Jittery; Nervousness; Wrong Technique In Device Usage Process  | Epipen         |                    |                    | S               | Intramuscular            | 0.3 Mg, Prn          |                 | Pfizer     |                |
|  | Epipen         |                    |                    | S               |                          |                      |                 | Pfizer     |                |
|  | Zyrtec         |                    |                    | C               |                          | Unk                  |                 |            |                |
|  | Levocetirizine |                    |                    | C               |                          | Unk                  |                 |            |                |

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|             |   |     |
|-------------|---|-----|
| Hydroxyzine | C | Unk |
| Hydroxyzine | C |     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 13-Mar-2017              | 13329919      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017106078 |                      | 81 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|---------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Expired Product Administered; Injection Site Bruising; Injection Site Pain | Epipen              |              |            | S           |              | Unk                |                 | Pfizer     |
|  | Coumadin /00014802/ |              |            | C           |              | Unk                |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 14-Mar-2017              | 13333351      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017105881 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Gait Disturbance      | Epipen         |              |            | S           |              | Unk Unk, Once      |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 15-Mar-2017              | 13159800      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1005046 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Expired Product Administered; Injection Site Hypoaesthesia; Injection Site Pain; Injury Associated With Device; Motor Dysfunction; Needle Issue; Neuralgia; Skeletal Injury; Tremor | Epipen Jr. Auto-Injector |              |            | S           |              | 0.15 Mg, Unk       |                 | Mylan      |
|   | Sertraline               |              |            | C           | Oral         | 100 Mg, Qd         |                 | Mylan      |
|   | Sertraline               |              |            | C           |              |                    |                 | Mylan      |
|   | Venlafaxine              |              |            | C           | Oral         | 75 Mg, Qd          |                 | Mylan      |
|   | Venlafaxine              |              |            | C           |              |                    |                 | Mylan      |
|   | Alprazolam               |              |            | C           |              | Unk                |                 | Mylan      |
|   | Alprazolam               |              |            | C           |              |                    |                 | Mylan      |
|   | Aspirin /00002701/       |              |            | C           |              | Unk                |                 | Mylan      |
|   | Meclizine /00072801/     |              |            | C           | Oral         | 25 Mg, Tid         |                 | Mylan      |
|   | Meclizine /00072801/     |              |            | C           |              |                    |                 | Mylan      |

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|                      |   |      |              |  |       |
|----------------------|---|------|--------------|--|-------|
| Meclizine /00072801/ | C |      |              |  | Mylan |
| Omeprazole           | C | Oral | 20 Mg, Qd    |  | Mylan |
| Vitamin D /00107901/ | C | Oral | 1000 N/A, Qd |  | Mylan |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 17-Mar-2017                       | 13347352               | EXPEDITED (15-DAY)        |                             | OT                       | GB-MYLANLABS-2017M1016934     |                               |                     | Unknown             | GBR                     |

| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--|---|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Malfunction; Injection Site Pain; Injury Associated With Device | Epipen (Epinephrine) Auto Injector 0.3 Mg |                       |                     | S                    |                       | Unk                         |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 20-Mar-2017                       | 13351101               | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017119649      |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Chest Pain                     | Epipen                  |                       |                     | S                    |                       | Unk                         |                          | Pfizer              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Mar-2017                       | 13361242               | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2017M1018049     |                               |                     | Unknown             | JPN                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Use Issue; Needle Issue | Epipen                  |                       |                     | S                    |                       |                             |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 22-Mar-2017                       | 13361267               | EXPEDITED (15-DAY)        |                             | DE, OT                   | AU-MYLANLABS-2017M1017795     |                               |                     | Unknown             | AUS                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Death; Drug Ineffective        | Epipen                  |                       |                     | S                    | Intramuscular         |                             |                          | Mylan               |



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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 23-Mar-2017   | 13272954       | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2017083172  |   | 15 YR           | Male       | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Coldness; Injection Site Ischaemia; Injection Site Pallor; Pain; Paraesthesia  | Epipen         |                    |                    | S               |                           | 0.3 Mg, Unk (0.3 Mg Of 1:1000 From An Epipen) |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Mar-2017   | 13364016       | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2017120389  |   | 9 YR            | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Coldness; Injection Site Ischaemia; Injection Site Pain; Injection Site Pallor; Injection Site Paraesthesia | Epipen         |                    |                    | S               |                           | 0.3 Mg Of 1:1000 Epinephrine                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Mar-2017   | 13366064       | EXPEDITED (15-DAY) |                    | HO, OT          | JP-MYLANLABS-2017M1018051 |   |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered; Injection Site Bruising; Needle Issue; Product Quality Issue  | Epipen         |                    |                    | S               |                           | Unk   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Mar-2017   | 13368239       | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2017083356  |   | 15 YR           | Male       | GBR            |

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| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Pallor; Peripheral Coldness | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Mar-2017   | 13377168             | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1019157 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Use Issue; Drug Dose Omission; Needle Issue          | Epipen               |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Mar-2017   | 13379541             | EXPEDITED (15-DAY) |                    | HO              | AU-MYLANLABS-2017M1019261 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen               |                    |                    | S               | Intramuscular             | 300 Mcg, Unk         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Mar-2017   | 13383270             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1018254 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Mar-2017   | 13384365             | EXPEDITED (15-DAY) |                    | LT, OT          | CA-MYLANLABS-2017M1019016 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>                                       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Jr            |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|---------------------------------------|---|-----------------|------------|----------------|
| 31-Mar-2017   | 13391995                               | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017139113              |   | 16 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen                                 |                    |                    | S               | Intramuscular                         | 0.3 Mg, Once  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Mar-2017   | 13393040                               | EXPEDITED (15-DAY) |                    | OT              | FR-SA-2017SA048383                    |   | 57 YR           | Female     | FRA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Cyanosis; Hypoaesthesia; Paraesthesia | Epipen                                 |                    |                    | S               | Intravenous (not otherwise specified) | Dosage Form: Infusion<br>Dose: 1:1000 Solution 0.3 MI; Around 80% Of The Whole Dose Was Infused |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Mar-2017   | 13395268                               | DIRECT             |                    | DS, HO, LT      |                                       |   | 18 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Product Quality Issue   | Epipen, 2-Pak<br>Quetiapine<br>Vyvanse |                    |                    | S<br>C<br>C     | Intramuscular                         | Quantity:1 Injection(S);  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Apr-2017   | 13395368                               | DIRECT             |                    | OT              |                                       |   | 30 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Quality Issue                               | Epipen 2-Pak (Epinephine) Auto-        |                    |                    | S               | Intramuscular                         | Quantity:2 Injection(S);  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2017   | 13394285                               | EXPEDITED (15-DAY) |                    | HO              | DK-MYLANLABS-                         |   |                 | Unknown    | DNK            |

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2017M1019841

| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure   | Epipen                                    |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2017  | 13394290                                  | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2017M1020299 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Panic Attack; Post-Traumatic Stress Disorder | Epipen                                    |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2017  | 13394295                                  | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2017M1019897 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen                                    |                    |                    | S               | Intramuscular             | 300 Mcg, Unk         |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2017  | 13394296                                  | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2017M1019257 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2017  | 13394401                                  | EXPEDITED (15-DAY) |                    | LT, OT          | CA-MYLANLABS-2017M1020597 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                         |                           |                             |                          |                               |                               |                             |                          |                         |  |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|--|
| Device Failure; Intentional Product Misuse                 |                         | Epipen Auto-Injector      |                             | S                        | Intramuscular                 |                               | 0.3 Mg, Prn                 |                          | Mylan                   |  |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 02-Apr-2017  | 13394402                | EXPEDITED (15-DAY)        |                             | HO, LT, OT               | US-MYLANLABS-2017M1020598     |                               |                             | Unknown                  | USA                     |  |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Device Failure   | Epipen Auto-Injector    |                           |                             |                          | S                             | Intramuscular                 | 0.3 Mg, Prn                 |                          | Mylan                   |  |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 02-Apr-2017  | 13395570                | DIRECT                    |                             | HO, LT                   |                               |                               | 37 YR                       | Unknown                  | USA                     |  |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Malaise; Product Quality Issue; Swelling Face              | Epipen                  |                           | Y                           |                          | S                             | Intramuscular                 |                             |                          |                         |  |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 02-Apr-2017  | 13395610                | DIRECT                    |                             | HO                       |                               |                               | 21 YR                       | Female                   | USA                     |  |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Condition Aggravated; Device Malfunction; Hypersensitivity | Epi-Pen                 |                           |                             |                          | S                             |                               |                             |                          |                         |  |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 02-Apr-2017  | 13395800                | DIRECT                    |                             | OT                       |                               |                               | 8 YR                        | Male                     | USA                     |  |
| <a href="#">Preferred Term</a>                             | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |  |
| Device Malfunction; Keloid Scar                            | Epipen                  |                           |                             |                          | S                             |                               |                             |                          | Mylan                   |  |
| <a href="#">FDA Received Date</a>                          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |  |
| 03-Apr-2017  | 13396070                | DIRECT                    |                             | OT                       |                               |                               | 15 YR                       | Female                   | USA                     |  |

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| <u>Preferred Term</u>                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|------------------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Malfunction                                      | Epi-Pen Auto Injector              |                    |                    | S               | Subcutaneous              |                      |                 | Mylan      |                |
|   | Asthma Inhaler                     |                    |                    | C               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Apr-2017   | 13361271                           | EXPEDITED (15-DAY) |                    | DE, HO          | AU-MYLANLABS-2017M1017780 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Condition Aggravated;<br>Device Issue; Drug Ineffective | Epipen                             |                    |                    | S               | Intramuscular             | 300 Microgram, Unk   |                 | Mylan      |                |
|   | Ventolin                           |                    |                    | S               |                           | Unk                  | Mylan           |            |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Apr-2017   | 13402571                           | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1020773 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Apnoea; Device Failure                                  | Epipen Auto-Injector               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Cyclobenzaprine Hydrochloride      |                    |                    | C               |                           | 5 Mg, Prn (10 Years) |                 |            |                |
|   | Hydrocodone Bitartrate/Paracetamol |                    |                    | C               |                           | 1000 Mg, Prn         |                 |            |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Apr-2017   | 13402573                           | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2017M1020615 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased                                   | Epipen Jr. Auto-Injector           |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>                      | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Apr-2017   | 13403572                           | DIRECT             |                    | LT              |                           |                      | 12 YR           | Male       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>                     | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                                  |                    |                    |                          |  |                           |                 |                                    |                |
|--|----------------------------------|--------------------|--------------------|--------------------------|--|---------------------------|-----------------|------------------------------------|----------------|
| Product Quality Issue;<br>Therapy Non-Responder                                | Epipen<br>Allegra Odt Children'S | S<br>C             | Intramuscular      | Quantity:1 Injection(S); |  | Mylan                     |                 |                                    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>   | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 05-Apr-2017  | 13371052                         | EXPEDITED (15-DAY) |                    | OT                       | NZ-MYLANLABS-<br>2017M1018496                                |                           |                 | Unknown                            | NZL            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                         |                |
| Device Failure; Device<br>Use Issue  | Epipen                           |                    |                    | S                        |  | Unk                       |                 | Mylan                              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>   | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 05-Apr-2017  | 13383372                         | EXPEDITED (15-DAY) |                    | DE, HO, OT               | AU-PFIZER INC-<br>2017126254                                 |                           |                 | Female                             | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                         |                |
| Device Issue; Drug<br>Ineffective  | Epipen 0.3mg<br>Ventolin         |                    |                    | S<br>S                   | Intramuscular  | 300 Microgram, Unk<br>Unk |                 | Pfizer                             |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>   | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 05-Apr-2017  | 13406335                         | EXPEDITED (15-DAY) |                    | HO, OT                   | US-MYLANLABS-<br>2017M1019366                                |                           |                 | Unknown                            | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                         |                |
| Device Failure   | Epipen Auto-Injector             |                    |                    | S                        |  | Unk                       |                 | Mylan                              |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>          | <u>Mfr Control #</u>   | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u>                         | <u>Country</u> |
| 05-Apr-2017  | 13407317                         | EXPEDITED (15-DAY) |                    | OT                       | FR-INTERNATIONAL<br>MEDICATION<br>SYSTEMS, LIMITED-<br>10650 |                           | 57 YR           | Female                             | FRA            |
| <u>Preferred Term</u>  | <u>Product</u>                   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>              | <u>Route</u>   | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u>                         |                |
| Accidental Exposure To<br>Product; Cyanosis;<br>Hypoaesthesia;<br>Paraesthesia | Epipen                           |                    |                    | S                        |  |                           |                 | International<br>Medication System |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 05-Apr-2017                                      | 13407436             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1021150 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|  | Flonase /00908302/   |                    |                    | C               |                           | Unk, Qd              |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Apr-2017                                      | 13407437             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1020886 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission               | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Apr-2017                                      | 13407438             | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2017M1020577 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission; Needle Issue | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Apr-2017                                      | 13408229             | DIRECT             | Y                  | DE              |                           |                      | 36 YR           | Female     | USA            |
| <u>Preferred Term</u>                            | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death  | Gammagard Liquid     |                    |                    | S               |                           | 25gm Every 4 Weeks   |                 |            |                |
|  | Epipen 0.3mg         |                    |                    | S               |                           | Peripheral           |                 |            |                |
| <u>FDA Received Date</u>                         | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Apr-2017                                      | 13409246             | DIRECT             |                    | LT              |                           |                      | 2 YR            | Male       | USA            |



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| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Malfunction             | Epipen Jr            |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Apr-2017                    | 13346724             | EXPEDITED (15-DAY) |                    | HO, OT          | AU-MYLANLABS-2017M1016641 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Issue; Drug Ineffective | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Apr-2017                    | 13411924             | EXPEDITED (15-DAY) |                    | DE, OT          | IE-PFIZER INC-2017146509  |                      |                 | Unknown    | IRL            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death                          | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Apr-2017                    | 13418861             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1021191 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                 | Epipen Auto-Injector |                    |                    | S               |                           | Unk, Prn             |                 | Mylan      |                |
|                                | Vitamins Nos         |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Apr-2017                    | 13418863             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1021183 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective               | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 06-Apr-2017   | 13418865                                  | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1021180 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Zyrtec                                    |                    |                    | C               | Oral                      | Unk, Qd              |                 | Mylan      |                |
|   | Qvar                                      |                    |                    | C               |                           | Unk, Bid             |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Apr-2017   | 13418866                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1021154 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue  | Epipen Jr. Auto-Injector                  |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Apr-2017   | 13418867                                  | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-MYLANLABS-2017M1021540 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector                      |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Apr-2017   | 13413095                                  | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2017M1019836 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|--------------------------|--|-----------------|------------|----------------|
| 07-Apr-2017   | 13415854                               | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017149071 |  |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Hypersensitivity; Incorrect Dose Administered; Weight Decreased  | Epipen                                 |                    |                    | S               |                          | Unk  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Apr-2017   | 13419711                               | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017149065 |  |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Skeletal Injury                       | Epipen                                 |                    |                    | S               |                          | Unk  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Apr-2017   | 13422505                               | DIRECT             | Y                  | HO              |                          |  | 59 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased   | Epipen 2-Pak Auto Injector 0.3mg/0.3ml |                    |                    | S               | Intramuscular            |  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>   | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2017   | 13364017                               | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2017120533 |  | 57 YR           | Female     | FRA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Cyanosis; Hypoaesthesia; Paraesthesia | Epipen                                 |                    |                    | S               |                          | 1:1000 Solution 0.3 MI; Around 80% Of The Whole Dose (0.3mg/0.3ml) |                 | Pfizer     |                |

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| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 10-Apr-2017              | 13421855             | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2017149079  |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen Jr            |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|                          | Zyrtec               |                    |                    | C               | Oral                      | Unk                  |                 |            |                |
|                          | Montelukast          |                    |                    | C               |                           | Unk                  |                 |            |                |
|                          | Symbicort            |                    |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2017              | 13424548             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1021896 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased    | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2017              | 13424549             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1022163 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2017              | 13424553             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1021466 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Apr-2017              | 13424556             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1021549 |                      |                 | Unknown    | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|--------------------------------|---------------------------|-----------------------------|--------------------------|--|-------------------------------|--------------------------|---------------------|-------------------------|
| Anaphylactic Reaction;<br>Device Failure                                 | Epipen Auto-Injector           |                           |                             | S                        | Intramuscular                              | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 10-Apr-2017  | 13424738                       | NON-EXPEDITED             |                             | HO                       | US-PFIZER INC-<br>2017149072               |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Effect Decreased  | Epipen Jr                      |                           |                             | S                        |  | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Apr-2017  | 13176731                       | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-<br>2017M1006448              |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Contusion; Injection Site<br>Scar; Injury Associated<br>With Device      | Epipen Jr. Auto-Injector       |                           |                             | S                        | Intramuscular                              | 0.15 Mg, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Apr-2017  | 13377165                       | EXPEDITED (15-DAY)        |                             | OT                       | PT-MYLANLABS-<br>2017M1018898              |                               |                          | Unknown             | PRT                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device<br>Use Issue; Drug Dose<br>Omission; Needle Issue | Epipen                         |                           |                             | S                        |  | 0.3 Mg, Unk                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>         | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>              | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 11-Apr-2017  | 13382394                       | EXPEDITED (15-DAY)        |                             | DE, HO, OT               | AU-<br>GLAXOSMITHKLINE-<br>AU2017GSK041115 |                               |                          | Female              | AUS                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>        | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                      | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Condition Aggravated;<br>Device Issue; Drug<br>Ineffective               | Ventolin<br>Epipen (Adrenalin) |                           |                             | S<br>S                   | Intramuscular                              | 300 Unk, Unk                  |                          | Glaxosmithkline     |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 11-Apr-2017   | 13417534       | EXPEDITED (15-DAY) |                    | DE, LT, OT      | CA-PFIZER INC-2017147111  |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death; Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue                      | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Apr-2017   | 13427070       | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2017M1021990 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Apr-2017   | 13427842       | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017149075  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Device Failure; Device Use Issue; Heart Rate Increased; Product Quality Issue | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|   | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Apr-2017   | 13427903       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017149066  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Issue; Drug Dose Omission; Haematoma; Product Quality Issue                      | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 11-Apr-2017   | 13429270                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1022175 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Apr-2017   | 13429394                 | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2017M1022142 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |
|   | Benadryl /00000402/      |                    |                    | C               |                           | 7.5 MI, Prn          |                 | Mylan      |                |
|   | Zyrtec                   |                    |                    | C               | Oral                      | 5 MI, Bid            |                 | Mylan      |                |
|   | Multivitamin /00097801/  |                    |                    | C               | Oral                      | 1 Df, Qd             |                 | Mylan      |                |
|   | Albuterol Hfa            |                    |                    | C               | Respiratory (inhalation)  | 2 Puffs Q4h          |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Apr-2017   | 12927625                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2016M1047122 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Laceration                     | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg/MI, Once      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Apr-2017   | 13356864                 | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1017364 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Use Issue; Product Leakage; Wrong Technique In Product | Epipen                   |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen                   |                    |                    | S               |                           |                      |                 | Mylan      |                |

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#### Usage Process

| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 12-Apr-2017   | 13430583                               | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017149409 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising   | Epipen                                 |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Apr-2017   | 13434337                               | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017151292 |                      | 60 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue | Epipen Jr                              |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Apr-2017   | 13435361                               | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017148972 |                      | 52 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Apnoea; Device Failure; Device Issue; Product Quality Issue                 | Epipen                                 |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Cyclobenzaprine Hydrochloride          |                    |                    | C               |                          | 5 Mg, Prn (10 Years) |                 |            |                |
|   | Acetaminophen W/Hydrocodone Bitartrate |                    |                    | C               |                          | 1000 Mg, Prn         |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017   | 13402502                               | EXPEDITED (15-DAY) |                    | DE, OT          | IE-PFIZER INC-2017146556 |                      |                 | Unknown    | IRL            |
| <u>Preferred Term</u>   | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death   | Epipen                                 |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |



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| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 13-Apr-2017              | 13424555             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1021902 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017              | 13434456             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2017M1022225 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017              | 13436138             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017153412  |                      | 14 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
|                          | Zyrtec               |                    |                    | C               | Oral                      | Unk, Qd              |                 |            |                |
|                          | Qvar                 |                    |                    | C               |                           | Unk, Bid             |                 |            |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017              | 13436140             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017153409  |                      | 27 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen Jr            |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017              | 13436163             | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2017153964  |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|   |                      |                    |                    |                 |                           |                      |                 |            |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective  | Epipen 0.3mg         |                    | S                  | Intramuscular   | 0.3 Mg, Prn               |                      | Pfizer          |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017   | 13436165             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017153407  |                      | 67 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Malaise; Vomiting   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|   | Lisinopril           |                    |                    | C               |                           | 20 Mg, Qd            |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017   | 13436167             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017153300  |                      | 55 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered; Product Storage Error | Epipen 0.3mg         |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017   | 13436170             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017155545  |                      | 24 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017   | 13439632             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1022850 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2017   | 13439639             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1022556 |                      |                 | Unknown    | USA            |

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| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | Unk Unk, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Apr-2017  | 13439643                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1022547     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Apr-2017  | 13439791                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1022866     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Apr-2017  | 12930269                | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2016523625      |                               | 18 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Laceration;<br>Product Quality Issue;<br>Vomiting | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Single                |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Apr-2017  | 13428350                | EXPEDITED (15-DAY)        |                             | DE                       | CA-PFIZER INC-2017148908      |                               |                          | Unknown             | CAN                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death; Expired Product Administered                              | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |

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| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|------------------------------------|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 14-Apr-2017                        | 13443058                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017161037      |                               | 7 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                   | Epipen                  |                           |                             | S                        |                               | 0.15 Mg, Unk                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Apr-2017                        | 13443175                | NON-EXPEDITED             |                             | LT, OT                   | US-PFIZER INC-2017157951      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Effect Decreased              | Epipen 0.3mg            |                           |                             | S                        |                               | 0.3 Mg, Unk                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Apr-2017                        | 13445221                | EXPEDITED (15-DAY)        |                             | DE                       | US-PFIZER INC-2017158805      |                               | 30 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death                              | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Apr-2017                        | 13424544                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1021538     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Apr-2017                        | 13446818                | NON-EXPEDITED             |                             | HO, OT                   | US-PFIZER INC-2017165174      |                               | 15 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                   | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Pfizer              |                         |

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| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------------|-----------------|------------|----------------|
| 17-Apr-2017  | 13447371             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023171 |                            |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                        |                 | Mylan      |                |
|  | Lisinopril           |                    |                    | C               |                           | 10 Mg, Qd                  |                 | Mylan      |                |
|  | Metoprolol           |                    |                    | C               |                           | 50 Mg, Qd                  |                 | Mylan      |                |
|  | Albuterol /00139501/ |                    |                    | C               |                           | 1-2 Puffs, 3-4 Times A Day |                 | Mylan      |                |
|  | Metformin            |                    |                    | C               |                           | 500 Mg, Qd                 |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2017  | 13448095             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-MYLANLABS-2017M1023152 |                            |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Cerebrovascular Accident; Drug Ineffective                   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once               |                 | Mylan      |                |
|  | Gabapentin           |                    |                    | C               |                           | 600 Mg, Tid                |                 | Mylan      |                |
|  | Topiramate           |                    |                    | C               |                           | 200 Mg, Bid                |                 | Mylan      |                |
| <u>FDA Received Date</u>                                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>       | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2017  | 13448104             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023491 |                            |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>         | <u>Duration</u> | <u>Mfr</u> |                |
| Arrhythmia; Heart Rate Increased; Regurgitation; Tachycardia | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk                |                 | Mylan      |                |
|  | Lyrica               |                    |                    | C               |                           | 225 Mg, Bid                |                 | Mylan      |                |
|  | Dimetapp /00048001/  |                    |                    | C               |                           | Unk                        |                 | Mylan      |                |
|  | Omeprazole           |                    |                    | C               |                           | Unk                        |                 | Mylan      |                |
|  | Nexium /01479302/    |                    |                    | C               |                           | Unk                        |                 | Mylan      |                |
|  | Depo Provera         |                    |                    | C               |                           | Unk                        |                 | Mylan      |                |

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| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 17-Apr-2017                            | 13449003             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023870 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure;<br>Pharyngeal Oedema   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Gabapentin           |                    |                    | C               |                           | 300 Mg, Tid          |                 | Mylan      |                |
|  | Verapamil            |                    |                    | C               |                           | 80 Mg, Tid           |                 | Mylan      |                |
|  | Metoprolol           |                    |                    | C               |                           | 200 Mg, Qd           |                 | Mylan      |                |
|  | Tramadol             |                    |                    | C               |                           | 100 Mg, Tid          |                 | Mylan      |                |
|  | Pravastatin          |                    |                    | C               |                           | 40 Mg, Qd            |                 | Mylan      |                |
|  | Omeprazol /00661201/ |                    |                    | C               |                           | 40 Mg, Qd            |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2017                            | 13449005             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1023186 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                       | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2017                            | 13449006             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1023185 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                         | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>               | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2017                            | 13439463             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017155544  |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>                  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |

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Ineffective; Product  
Quality Issue

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 18-Apr-2017  | 13443061             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-<br>2017158803  |                      | 16 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen 0.3mg         |                    |                    | S               |                               | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2017  | 13455120             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-<br>2017163581  |                      | 41 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen               |                    |                    | S               |                               | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2017  | 13456269             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-<br>2017M1023485 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain Upper;<br>Diarrhoea; Loss Of<br>Consciousness; Vomiting | Epipen Auto-Injector |                    |                    | S               | Intramuscular                 | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2017  | 13456270             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-<br>2017M1023490 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               |                               | Unk Unk, Once        |                 | Mylan      |                |
|  | Epipen Auto-Injector |                    |                    | S               |                               |                      |                 | Mylan      |                |
|  | Depo-Provera         |                    |                    | C               |                               |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|--------------------------|-----------------|------------|----------------|
| 18-Apr-2017   | 13456271                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023897 |                          |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Ear Swelling; Swelling  | Epipen Auto-Injector     |                    |                    | S               |                           | 0.3 Mg, Once             |                 | Mylan      |                |
|   | Lisinopril               |                    |                    | C               |                           | 20 Mg, Qd                |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2017   | 13456275                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023896 |                          |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2017   | 13457137                 | DIRECT             |                    | HO, LT          |                           |                          | 25 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Hypersensitivity; Pharyngeal Oedema; Product Quality Issue; Swelling Face | Epi Pen                  |                    |                    | S               | Intramuscular             | Quantity:2 Injection(S); |                 | Mylan      |                |
|   | Flovent                  |                    |                    | C               |                           |                          |                 |            |                |
|   | Proair                   |                    |                    | C               |                           |                          |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>     | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2017   | 13457230                 | DIRECT             | Y                  | OT              |                           |                          | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>       | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction; Drug Dose Omission; Injection Site Laceration; Needle Issue             | Epipen Jr                |                    |                    | S               |                           |                          |                 |            |                |
|   | Advair                   |                    |                    | C               |                           |                          |                 |            |                |
|   | Allegra                  |                    |                    | C               |                           |                          |                 |            |                |
|   | Albuterol Nebulizer      |                    |                    | C               |                           |                          |                 |            |                |
|   | Proair                   |                    |                    | C               |                           |                          |                 |            |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2017               | 12745450       | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2016422924 |                      | 42 YR           | Female     | USA            |
| <u>Preferred Term</u>     | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Hyperventilation | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2017  | 13428906       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1021948 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Breakage; Device Failure; Device Use Issue; Drug Dose Omission; Limb Injury | Epipen         |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2017   | 13439872       | NON-EXPEDITED    |                    | LT, OT          | US-PFIZER INC-2017155542 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue | Epipen Jr      |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2017   | 13455158       | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2017157953 |                      | 62 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Injection Site Bruising; Injection Site Haematoma; Injection Site Pain; Product Quality Issue | Epipen         |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2017                               | 13458109             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023895 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                          | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Cetirizine           |                    |                    | C               |                           | 10 Mg, Qd            |                 | Mylan      |                |
|   | Prednisone           |                    |                    | C               |                           | 10 Mg, Tid           |                 | Mylan      |                |
|   | Montelukast          |                    |                    | C               |                           | 10 Mg, Pm            |                 | Mylan      |                |
|   | Proair /00139502/    |                    |                    | C               |                           | 2 Puffs, Qid         |                 | Mylan      |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Apr-2017                               | 13458111             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1023899 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                          | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Cetirizine           |                    |                    | C               |                           | 10 Mg, Qd            |                 | Mylan      |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Apr-2017                               | 13458112             | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-MYLANLABS-2017M1023520 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cerebrovascular Accident; Seizure         | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Reglan /00041901/    |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Apr-2017                               | 13458123             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2017M1023902 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective; Product | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|               |                   |   |              |       |
|---------------|-------------------|---|--------------|-------|
| Storage Error | Hydroxyzine       | C | 10 Mg, Prn   | Mylan |
|               | Albuterol Sulfate | C | 1.25 Mg, Prn | Mylan |
|               | Spironolactone    | C | 50 Mg, Qd    | Mylan |
|               | Famotidine        | C | 20 Mg, Bid   | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Apr-2017              | 13459381             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1023912 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|                          | Levothyroxine        |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 20-Apr-2017              | 13439641            | EXPEDITED (15-DAY) |                    | LT, OT          | CA-MYLANLABS-2017M1022858 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>    | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective         | Epipen              |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
|                          | Benadryl /00000402/ |                    |                    | S               | Intramuscular             | 25 Mg, Unk           |                 | Mylan      |                |

| <u>FDA Received Date</u>                            | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 20-Apr-2017   | 13446794                                  | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1023307 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>                               | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Product Use Issue | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 20-Apr-2017              | 13452173       | EXPEDITED (15-DAY) |                    | OT              | CZ-MYLANLABS-2017M1023308 |                      |                 | Unknown    | CZE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

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### Detailed Report

|  |                        |                    |                    |                 |                           |                      |                 |            |                |
|--|------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Needle Issue                 |                        | Epipen             |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Apr-2017                                  | 13460413               | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017163121  |                      | 26 YR           | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                             | Epipen Jr              |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Apr-2017                                  | 13460424               | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017165743  |                      | 44 YR           | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                             | Epipen                 |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Apr-2017                                  | 13461869               | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017165151  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pulmonary Embolism; Thrombosis               | Epipen                 |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|  | Humira                 |                    |                    | S               | Subcutaneous              | Unk                  |                 |            |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Apr-2017                                  | 13461885               | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023920 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Hypersensitivity; Pruritus | Epipen Auto-Injector   |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| Generalised; Rash                            | Metformin              |                    |                    | C               |                           | 5 Mg, Qd             |                 | Mylan      |                |
| Generalised; Skin Discolouration             | Insulin                |                    |                    | C               |                           |                      |                 | Mylan      |                |
|  | Isosorbide Mononitrate |                    |                    | C               |                           | 30 Mg, Qd            |                 | Mylan      |                |
|  | Advil /00109201/       |                    |                    | C               |                           | 250 Mg, Qd           |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                      |   |            |       |
|----------------------|---|------------|-------|
| Vitamin E /00110501/ | S | 40 Mg, Qd  | Mylan |
| Sucralfate           | C | 1 Df, Qd   | Mylan |
| Losartan             | C | 100 Mg, Qd | Mylan |
| Aspirin /00002701/   | C | 350 Mg, Qd | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 20-Apr-2017              | 13464891      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023190 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure; Drug Ineffective; Wrong Technique In Device Usage Process | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Once       |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Apr-2017              | 13465989      | NON-EXPEDITED    |                    | LT, OT          | US-PFIZER INC-2017170603 |                      | 65 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Drug Ineffective      | Epipen         |              |            | S           | Intramuscular | 0.3 Mg, Once       |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Apr-2017              | 13465991      | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2017170541 |                      |            | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u>     | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|------------------------|-----------------|------------|
| Drug Ineffective      | Epipen         |              |            | S           |              | Unk                    |                 | Pfizer     |
|                       | Levemir        |              |            | C           |              | 23 Units               |                 |            |
|                       | Humalog        |              |            | C           |              | 3-6 Units Before Meals |                 |            |
|                       | Vyvanse        |              |            | C           |              | 60 Mg, Qd              |                 |            |
|                       | Montelukast    |              |            | C           |              | 10 Mg, Qd              |                 |            |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 21-Apr-2017               | 13468474             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1023889 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective          | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Apr-2017               | 13468475             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1024302 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure            | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
|                           | Percocet /00446701/  |                    |                    | C               |                           | 7.5 Mg, Tid          |                 | Mylan      |                |
|                           | Zanaflex             |                    |                    | C               |                           | 2 Mg, Bid            |                 | Mylan      |                |
|                           | Atenolol             |                    |                    | C               |                           | 25 Mg, Qd            |                 | Mylan      |                |
|                           | Levothyroxine        |                    |                    | C               |                           | 0.25 Mg, Qd          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Apr-2017               | 13468477             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1024166 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective          | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
|                           | Nuvaring             |                    |                    | C               |                           | 0.015 Mg, Qd         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Apr-2017               | 13468510             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-PFIZER INC-2017170450  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cerebrovascular Accident; | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| Drug Ineffective; Hypoxia | Gabapentin           |                    |                    | C               |                           | 600 Mg, Tid          |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Topiramate

C

200 Mg, Bid

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Apr-2017              | 13468708      | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017170538 |                      | 43 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; Device Use Issue; Needle Issue; Pharyngeal Oedema | Epipen               |              |            | S           |              | Unk                |                 | Pfizer     |
|   | Gabapentin           |              |            | C           |              | 300 Mg, Tid        |                 |            |
|   | Verapamil            |              |            | C           |              | 80 Mg, Tid         |                 |            |
|   | Metoprolol           |              |            | C           |              | 200 Mg, Qd         |                 |            |
|   | Tramadol             |              |            | C           |              | 100 Mg, Tid        |                 |            |
|   | Pravastatin          |              |            | C           |              | 40 Mg, Qd          |                 |            |
|   | Omeprazol /00661201/ |              |            | C           |              | 40 Mg, Qd          |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 21-Apr-2017              | 13469235      | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017172507 |                      | 56 YR      | Male       | USA            |

| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Abdominal Pain Upper; Diarrhoea; Loss Of Consciousness; Vomiting | Epipen         |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Apr-2017              | 13418860      | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1021541 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|------------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; Drug Dose Omission | Epipen Auto-Injector |              |            | S           |              | Unk                |                 | Mylan      |
|                                    | Epipen Auto-Injector |              |            | S           |              |                    |                 | Mylan      |
|                                    | Epipen Auto-Injector |              |            | S           |              |                    |                 | Mylan      |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 24-Apr-2017  | 13472778       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017170540 |                      | 68 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Injection Site Haemorrhage; Injection Site Laceration; Product Quality Issue; Wrong Technique In Product Usage Process | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|  | Benicar        |                    |                    | C               |                          | 5 Mg, Qd             |                 |            |                |
|  | Janumet        |                    |                    | C               |                          | 50-100mg, Bid        |                 |            |                |
|  | Glipizide      |                    |                    | C               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017  | 13472779       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017172508 |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Injection Site Pain; Product Quality Issue; Underdose  | Epipen 0.3mg   |                    |                    | S               | Intramuscular            | Unk Unk, Once        |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017  | 13472781       | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017170602 |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue  | Epipen         |                    |                    | S               | Intramuscular            | Unk Unk, Once        |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017  | 13472803       | EXPEDITED (15-DAY) |                    | DS, HO, OT      | US-PFIZER INC-2017174040 |                      | 32 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|                                      |                               |                    |                    |                 |                               |                      |                 |            |                |
|--------------------------------------|-------------------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Cerebrovascular Accident;<br>Seizure | Epipen<br>Reglan /00041901/   | S<br>S             |                    |                 |                               | 0.3 Mg, Once<br>Unk  |                 | Pfizer     |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017                          | 13473148                      | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-<br>2017174919  |                      | 55 YR           | Female     | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                     | Epipen 0.3mg<br>Levothyroxine |                    |                    | S<br>C          | Intramuscular                 | 0.3 Mg, Prn<br>Unk   |                 | Pfizer     |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017                          | 13473761                      | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-<br>2017M1024624 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                       | Epipen                        |                    |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017                          | 13473764                      | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-<br>2017M1024287 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                     | Epipen Auto-Injector          |                    |                    | S               |                               | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017                          | 13474307                      | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2017172937  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Malaise                              | Epipen                        |                    |                    | S               |                               | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>             | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Apr-2017                          | 13474595                      | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2017176247  |                      | 58 YR           | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|------------------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective;<br>Hypersensitivity; Pruritus<br>Generalised; Rash<br>Generalised; Skin<br>Discolouration                                       | Epipen 0.3mg           |                    |                    | S               | Intramuscular                | 0.3 Mg, Prn          |                 | Pfizer     |                |
|   | Vitamin E /00110501/   |                    |                    | C               |                              | 40 Mg, Qd            |                 |            |                |
|   | Metformin              |                    |                    | C               |                              | 5 Mg, Qd             |                 |            |                |
|   | Insulin                |                    |                    | C               |                              | Unk                  |                 |            |                |
|   | Isosorbide Mononitrate |                    |                    | C               |                              | 30 Mg, Qd            |                 |            |                |
|   | Advil /00109201/       |                    |                    | C               |                              | 250 Mg, Qd           |                 |            |                |
|   | Sucralfate             |                    |                    | C               |                              | 1 Df, Qd             |                 |            |                |
|   | Losartan               |                    |                    | C               |                              | 100 Mg, Qd           |                 |            |                |
|   | Aspirin /00002701/     |                    |                    | C               |                              | 350 Mg, Qd           |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Apr-2017   | 13457084               | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-<br>2017170447 |                      | 54 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Back Disorder;<br>Device Failure; Device<br>Use Issue; Injection Site<br>Haemorrhage; Product<br>Quality Issue | Epipen 0.3mg           |                    |                    | S               | Intramuscular                | 0.3 Mg, Prn          |                 | Pfizer     |                |
|   |                        |                    |                    |                 |                              |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Apr-2017   | 13477121               | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2017172935 |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Ear<br>Swelling; Swelling   | Epipen 0.3mg           |                    |                    | S               |                              | 0.3 Mg, Once         |                 | Pfizer     |                |
|   | Lisinopril             |                    |                    | C               |                              | 20 Mg, Qd            |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Apr-2017   | 13478521               | NON-EXPEDITED      |                    | HO, OT          | US-PFIZER INC-<br>2017174038 |                      | 46 YR           | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|-------------------|------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue; Product Storage Error | Epipen            |                  |                    | S               | Intramuscular            | Once                 |                 | Pfizer     |                |
|  | Hydroxyzine       |                  |                    | C               |                          | 10 Mg, Prn           |                 |            |                |
|  | Albuterol Sulfate |                  |                    | C               |                          | 1.25 Mg, Prn         |                 |            |                |
|  | Spironolactone    |                  |                    | C               |                          | 50 Mg, Qd            |                 |            |                |
|  | Famotidine        |                  |                    | C               |                          | 20 Mg, Bid           |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Apr-2017  | 13478610          | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2017176209 |                      | 9 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Oral Disorder; Product Quality Issue                           | Epipen            |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Apr-2017  | 13478860          | NON-EXPEDITED    |                    | LT, OT          | US-PFIZER INC-2017153374 |                      | 17 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue                      | Epipen            |                  |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|  | Epipen            |                  |                    | S               |                          |                      | Pfizer          |            |                |
|  | Epipen            |                  |                    | S               |                          |                      | Pfizer          |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Apr-2017  | 13485429          | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2017174039 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen            |                  |                    | S               |                          | 0.3 Mg, Once         |                 | Pfizer     |                |
|  | Cetirizine        |                  |                    | C               |                          | 10 Mg, Qd            |                 |            |                |
|  | Prednisone        |                  |                    | C               |                          | 10 Mg, Tid           |                 |            |                |
|  | Montelukast       |                  |                    | C               |                          | 10 Mg, Pm            |                 |            |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Proair /00139502/

C

2 Puffs, Qid

| <a href="#">FDA Received Date</a>              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-Apr-2017                                    | 13485479                | NON-EXPEDITED             |                             | LT, OT                   | US-PFIZER INC-2017174042      |                               | 15 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                               | Epipen                  |                           |                             | S                        |                               | 0.3 Mg, Once                  |                          | Pfizer              |                         |
|  | Cetirizine              |                           |                             | C                        |                               | 10 Mg, Qd                     |                          |                     |                         |
| <a href="#">FDA Received Date</a>              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Apr-2017                                    | 13484551                | NON-EXPEDITED             |                             | LT, OT                   | US-PFIZER INC-2017181135      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                               | Epipen                  |                           |                             | S                        |                               | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Apr-2017                                    | 13486250                | EXPEDITED (15-DAY)        |                             | HO, LT                   | NL-MYLANLABS-2017M1025528     |                               |                          | Unknown             | NLD                     |
| <a href="#">Preferred Term</a>                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Malfunction; Drug Ineffective; Dyspnoea | Epipen Auto-Injector    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Apr-2017                                    | 13486262                | EXPEDITED (15-DAY)        |                             | HO, OT                   | US-MYLANLABS-2017M1024907     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Ineffective               | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Apr-2017                                    | 13486273                | EXPEDITED (15-DAY)        |                             | LT                       | US-MYLANLABS-2017M1024908     |                               |                          | Unknown             | USA                     |

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| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Drug Dose Omission; Wrong Technique In Product Usage Process   | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Apr-2017  | 13473778             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017176245  |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Injection Site Haemorrhage   | Epipen Jr            |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Apr-2017  | 13489404             | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2017180745  |                      | 17 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising; Injection Site Swelling; Limb Mass; Pain In Extremity; Vascular Pseudoaneurysm; Yellow Skin | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Apr-2017  | 13490584             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1024541 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Apr-2017  | 13492247             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017178698  |                      | 39 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                     |                    |                    |                 |                           |                      |                 |            |                |
|--|---------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective   | Epipen              |                    | S                  |                 | 0.3 Mg, Once              |                      | Pfizer          |            |                |
|  | Benadryl /00000402/ |                    | S                  |                 | 1 Df, Once                |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Apr-2017  | 13495279            | DIRECT             |                    | DE              |                           |                      | 31 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death  | Epi-Pen             |                    |                    | S               | Intramuscular             |                      |                 | Meridian   |                |
|  | Breo                |                    |                    | C               |                           |                      |                 |            |                |
|  | Albuterol Inhalers  |                    |                    | C               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2017  | 13494779            | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017181168  |                      | 43 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Paraesthesia; Injection Site Warmth | Epipen 0.3mg        |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2017  | 13494829            | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017178578  |                      | 30 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Feeling Hot; Paraesthesia; Paraesthesia Oral   | Epipen              |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
|  | Nuvaring            |                    |                    | C               |                           | 0.015 Mg, Qd         |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2017  | 13495662            | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1023960 |                      |                 | Unknown    | DOM            |
| <u>Preferred Term</u>  | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                      |                      |                    |                 |                           |                      |                 |            |                |
|--|----------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure   |                      | Epipen Auto-Injector |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2017  | 13496788             | NON-EXPEDITED        |                    | OT              | US-PFIZER INC-2017178579  |                      | 21 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Effect Incomplete; Product Quality Issue  | Epipen               |                      |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|  | Rifabutin            |                      |                    | C               |                           | Unk                  |                 |            |                |
|  | Xarelto              |                      |                    | C               |                           | 20 Mg, Qd            |                 |            |                |
|  | Trileptal            |                      |                    | C               |                           | 100 Mg, Bid          |                 |            |                |
|  | Cipro /00697201/     |                      |                    | C               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2017  | 13497158             | EXPEDITED (15-DAY)   |                    | OT              | US-PFIZER INC-2017187812  |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Device Failure; Device Use Issue; Injection Site Discolouration; Injection Site Hypoaesthesia; Product Quality Issue | Epipen               |                      |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2017  | 13497319             | EXPEDITED (15-DAY)   |                    | OT              | US-MYLANLABS-2017M1025441 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen Auto-Injector |                      |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Apr-2017  | 13497685             | NON-EXPEDITED        |                    | HO, OT          | US-PFIZER INC-2017185369  |                      | 59 YR           | Male       | USA            |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue               | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 28-Apr-2017   | 13497757                | EXPEDITED (15-DAY)        |                             | HO, LT                   | NL-PFIZER INC-2017186876      |                               |                          | Female              | NLD                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Malfunction; Device Use Issue; Drug Ineffective; Dyspnoea; Product Quality Issue | Epipen 0.3mg            |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-May-2017   | 13472782                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017170542      |                               | 59 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Error; Drug Ineffective; Product Quality Issue               | Epipen 0.3mg            |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-May-2017   | 13500494                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017180955      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Issue; Drug Dose Omission; Rash                              | Epipen                  |                           |                             | S                        |                               | Unk Unk, Once                 |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-May-2017   | 13500602                | NON-EXPEDITED             |                             | DE, OT                   | US-PFIZER INC-2017189935      |                               |                          | Female              | USA                     |



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| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective                        | Epipen                   |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-May-2017                             | 13500604                 | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017187720  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                        | Epipen 0.3mg             |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-May-2017                             | 13500609                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017190136  |                      | 4 YR            | Male       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child | Epipen Jr                |                    |                    | S               | Intramuscular             | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-May-2017                             | 13456273                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1023494 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective        | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-May-2017                             | 13504439                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1025731 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission      | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
|   | Cromoglicate Sodium      |                    |                    | C               | Oral                      | Unk                  |                 |            |                |
|   | Diphenhydramine          |                    |                    | C               |                           | Q2-4h                |                 |            |                |
|   | Aluminium Hydroxide Gel, |                    |                    | C               |                           | 40 Mg, Qd            |                 |            |                |

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|                           |   |            |
|---------------------------|---|------------|
| Dried/Magnesium Carbonate | C | 30 Mg, Unk |
| Duloxetine Hydrochloride  | C | Unk, Qd    |
| Salbutamol                | C |            |
| Ipratropium               | C |            |
| Prednisone                | C | Unk, Qd    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 02-May-2017              | 13504441      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1025704 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>                          | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|--|--------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Drug Ineffective; Expired Product Administered | Epipen Jr. Auto-Injector |              |            | S           | Intramuscular | 0.15 Mg, Prn       |                 | Mylan      |
|  | Epipen Jr. Auto-Injector |              |            | S           |               |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 03-May-2017              | 13507960      | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2017189815 |                      | 41 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u>         | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Drug Ineffective      | Epipen                 |              |            | S           |              | Unk                |                 | Pfizer     |
|                       | Epipen                 |              |            | S           |              | Unk                |                 | Pfizer     |
|                       | Azithromycin           |              |            | C           |              | Unk, Qd            |                 |            |
|                       | Doxycycline /00055701/ |              |            | C           |              | 200 Mg, Bid        |                 |            |
|                       | Plaquenil /00072602/   |              |            | C           |              | Unk, Qd            |                 |            |
|                       | Heparin                |              |            | C           |              | Unk                |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 04-May-2017              | 13513907      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1026103 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u> | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure        | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Mylan      |
|                       | Hydralazine          |              |            | C           |               | 25 Mg, Tid         |                 | Mylan      |
|                       | Losartan             |              |            | C           |               | 10 Mg, Qd          |                 | Mylan      |

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|   | Amlodipine               | C                  |                    | 10 Mg, Qd       |                           |                      |                 | Mylan      |                |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
|   | Carvedilol               | C                  |                    | 25 Mg, Bid      |                           |                      |                 | Mylan      |                |
|   | Metformin                | C                  |                    | 500 Mg, Bid     |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-May-2017   | 13514508                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1025951 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-May-2017   | 13514510                 | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-MYLANLABS-2017M1026238 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-May-2017   | 13515589                 | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017193984  |                      | 45 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Needle Issue; Product Quality Issue | Epipen                   |                    |                    | S               | Intramuscular             | Unk, Single          |                 | Pfizer     |                |
|   | Cromoglicate Sodium      |                    |                    | C               | Oral                      | Unk                  |                 |            |                |
|   | Diphenhydramine          |                    |                    | C               |                           | Q2-4h                |                 |            |                |
|   | Alcabo                   |                    |                    | C               |                           | 40 Mg, Qd            |                 |            |                |
|   | Duloxetine Hydrochloride |                    |                    | C               |                           | 30 Mg, Unk           |                 |            |                |
|   | Salbutamol               |                    |                    | C               |                           | Unk, Qd              |                 |            |                |
|   | Ipratropium              |                    |                    | C               |                           |                      |                 |            |                |
|   | Prednisone               |                    |                    | C               |                           | Unk, Qd              |                 |            |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 05-May-2017                                    | 13516826             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017193988  |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered | Epipen Jr            |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Pfizer     |                |
|  | Epipen Jr            |                    |                    | S               |                           |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-May-2017                                    | 13516941             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017196643  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                               | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-May-2017                                    | 13518881             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1026356 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective               | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-May-2017                                    | 13519066             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1026413 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                 | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|  | Aspirin /00002701/   |                    |                    | C               |                           | 81 Mg, Qd            |                 | Mylan      |                |
|  | Nexium /01479302/    |                    |                    | C               |                           | 20 Mg, Bid           |                 | Mylan      |                |
|  | Norvasc              |                    |                    | C               |                           | 5 Mg, Qd             |                 | Mylan      |                |
|  | Synthroid            |                    |                    | C               |                           | 50 Mg, Qd            |                 | Mylan      |                |
|  | Metoprolol           |                    |                    | C               |                           | 25 Mg, Qd            |                 | Mylan      |                |

# FDA Adverse Event Reporting System

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|            |   |             |       |
|------------|---|-------------|-------|
| Lorazepam  | C | 0.5 Mg, Prn | Mylan |
| Sertraline | C | 50 Mg, Qd   | Mylan |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-May-2017                       | 13519121               | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1026663     |                               |                     | Unknown             | USA                     |

| <a href="#">Preferred Term</a>     | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|------------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure; Drug Dose Omission | Epipen Auto-Injector    |                       |                     | S                    | Intramuscular         | Unk Unk, Prn                |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-May-2017                       | 13519214               | EXPEDITED (15-DAY)        |                             | OT                       | JP-PFIZER INC-2017147147      |                               | 9 YR                | Male                | JPN                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Anaphylactic Shock; Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen 0.3mg            |                       |                     | S                    |                       | Unk                         |                          | Pfizer              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-May-2017                       | 13519225               | NON-EXPEDITED             |                             | HO, LT, OT               | US-PFIZER INC-2017199092      |                               | 59 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen                  |                       |                     | S                    | Intramuscular         | 0.3 Mg, Once                |                          | Pfizer              |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 05-May-2017                       | 13519312               | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017199091      |                               | 13 YR               | Male                | USA                     |

| <a href="#">Preferred Term</a> | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
|--------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |        |   |     |        |
|--|--------|---|-----|--------|
| Accidental Exposure To Product; Expired Product Administered; Injection Site Bruising; Injection Site Injury | Epipen | S | Unk | Pfizer |
|--|--------|---|-----|--------|

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 08-May-2017              | 13522348      | DIRECT           |                    | OT              |                      |                      | 7 YR       | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u>                     | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|------------------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product By Child; Injection Site Pain; Injection Site Swelling; Wrist Fracture | Epi-Pen Jr.<br>Claritin<br>Flonase |              |            | S<br>C<br>C | Subcutaneous |                    |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 08-May-2017              | 13523043      | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1026667 |                      |            | Unknown    | USA            |

| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|----------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Device Failure; Drug Ineffective | Epipen Auto-Injector |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 08-May-2017              | 13524557      | NON-EXPEDITED    |                    | OT              | US-PFIZER INC-2017200906 |                      | 58 YR      | Female     | USA            |

| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |
|--|----------------------|--------------|------------|-------------|---------------|---------------------------|-----------------|------------|
| Drug Ineffective For Unapproved Indication; Injection Site Pain; Musculoskeletal Stiffness | Epipen<br>Prednisone |              |            | S<br>S      | Intramuscular | 0.3 Mg, Once<br>5 Mg, Prn |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 09-May-2017              | 13486623      | NON-EXPEDITED    |                    | HO, LT, OT      | US-PFIZER INC-2017178577 |                      | 13 YR      | Male       | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|

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|   |                |                    |                    |                 |                          |                      |                 |            |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective  | Epipen         |                    | S                  | Intramuscular   | 0.3 Mg, Once             |                      | Pfizer          |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-May-2017   | 13497579       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017187723 |                      | 30 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen 0.3mg   |                    |                    | S               |                          | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-May-2017   | 13527732       | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017200798 |                      | 365 DAY         | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cyanosis; Furuncle; Vomiting  | Epipen         |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-May-2017   | 13528386       | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017201091 |                      | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue   | Epipen         |                    |                    | S               |                          | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-May-2017   | 13528387       | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017200897 |                      | 13 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue | Epipen         |                    |                    | S               | Intramuscular            | Unk Unk, Prn         |                 | Pfizer     |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 09-May-2017   | 13528604             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017203051  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Ineffective; Needle Issue; Product Quality Issue       | Epipen 0.3mg         |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-May-2017   | 13434465             | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1022917 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock; Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-May-2017   | 13471564             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017172505  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue                     | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-May-2017   | 13537128             | EXPEDITED (15-DAY) |                    | DE              | US-MYLANLABS-2017M1027536 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |



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|                     |   |      |              |       |
|---------------------|---|------|--------------|-------|
| Aspirin /00002701/  | C | Oral | 81 Mg, Qd    | Mylan |
| Claritin /00917501/ | C |      | Unk          | Mylan |
| Coreg               | C | Oral | 6.25 Mg, Bid | Mylan |
| Lisinopril          | C | Oral | 10 Mg, Qd    | Mylan |
| Flonase             | C |      | Unk          | Mylan |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-May-2017              | 13176901      | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017040017 |                      | 16 YR      | Male       | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Accidental Exposure To Product; Chest Pain; Disturbance In Attention; Expired Product Administered; Feeling Jittery; Headache; Injection Site Bruising; Injection Site Pain | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-May-2017              | 13497701      | NON-EXPEDITED    |                    | LT              | US-PFIZER INC-2017185370 |                      | 68 YR      | Female     | USA            |

| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|---|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; Drug Dose Omission; Product Quality Issue; Wrong Technique In Product Usage Process | Epipen         |              |            | S           |              | Unk                |                 | Pfizer     |
|   | Epipen         |              |            | S           |              | 0.3 Mg, Unk        |                 | Pfizer     |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 12-May-2017              | 13519321      | NON-EXPEDITED    |                    | LT, OT          | US-PFIZER INC-2017199089 |                      | 13 YR      | Female     | USA            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Drug Ineffective      | Epipen 0.3mg   |              |            | S           | Intramuscular | 0.3 Mg, Prn        |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-May-2017  | 13539286             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017207830  |                      | 39 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
|  | Prazosin             |                    |                    | C               |                           | 1 Mg, Qd             |                 |            |                |
|  | Mirtazapine          |                    |                    | C               |                           | 15 Mg, Qd            |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-May-2017  | 13541449             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017207829  |                      | 54 YR           | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Dizziness; Expired Product Administered; Hyperhidrosis; Injection Site Hypoaesthesia; Palpitations | Epipen               |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-May-2017  | 13541984             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1027550 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-May-2017  | 12680262             | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2016379502  |                      | 80 YR           | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Confusional State; Decreased Appetite;   | Epipen               |                    |                    | S               |                           | Unk, As Needed       |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Dizziness; Dysgeusia;  
Dyspnoea; Emotional  
Disorder; Epistaxis;  
Headache; Hypertension;  
Palpitations; Parosmia;  
Tremor

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 15-May-2017   | 13473762                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1023933 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Laceration                                 | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-May-2017   | 13406650                 | EXPEDITED (15-DAY) |                    | HO, OT          | JP-MYLANLABS-2017M1020981 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Use Issue; Needle Issue; Therapeutic Response Decreased            | Epipen                   |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-May-2017   | 13515545                 | NON-EXPEDITED      |                    | DE              | US-PFIZER INC-2017189895  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen                   |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-May-2017   | 13548878                 | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017212575  |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|   |                     |                    |                    |                 |                          |                      |                 |            |                |
|---|---------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product By Child; Injection Site Coldness  |                     | Epipen             |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-May-2017   | 13549931            | NON-EXPEDITED      |                    | DE              | US-PFIZER INC-2017210377 |                      | 64 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Needle Issue; Product Quality Issue                   | Epipen              |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen              |                    |                    | S               |                          |                      |                 | Pfizer     |                |
|   | Aspirin /00002701/  |                    |                    | C               | Oral                     | 81 Mg, Qd            |                 |            |                |
|   | Claritin /00917501/ |                    |                    | C               |                          | Unk                  |                 |            |                |
|   | Coreg               |                    |                    | C               | Oral                     | 6.25 Mg, Bid         |                 |            |                |
|   | Lisinopril          |                    |                    | C               | Oral                     | 10 Mg, Qd            |                 |            |                |
|   | Flonase             |                    |                    | C               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-May-2017   | 13551805            | EXPEDITED (15-DAY) |                    | LT, OT          | US-PFIZER INC-2017180734 |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Injection Site Laceration; Needle Issue; Product Quality Issue; Underdose | Epipen Jr           |                    |                    | S               | Intramuscular            | Unk Unk, Once        |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-May-2017   | 13406968            | EXPEDITED (15-DAY) |                    | OT              | GB-PFIZER INC-2017149441 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Panic Attack; Post-Traumatic Stress Disorder; Product Quality             | Epipen              |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Issue

| <u>FDA Received Date</u>           | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-May-2017                        | 13434141                                  | EXPEDITED (15-DAY) |                    | OT              | IE-MYLANLABS-2017M1022743 |                      |                 | Unknown    | IRL            |
| <u>Preferred Term</u>              | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                     | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-May-2017                        | 13434454                                  | EXPEDITED (15-DAY) |                    | HO, LT          | IE-MYLANLABS-2017M1021995 |                      |                 | Unknown    | IRL            |
| <u>Preferred Term</u>              | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                     | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
|                                    | Symbicort                                 |                    |                    | C               | Respiratory (inhalation)  | Unk Unk, Prn         |                 | Mylan      |                |
|                                    | Ventoline /00139501/                      |                    |                    | C               | Respiratory (inhalation)  | Unk Unk, Prn         |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-May-2017                        | 13561398                                  | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1028766 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>              | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                   | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-May-2017                        | 13561539                                  | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1029005 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>              | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission | Epipen Auto-Injector                      |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

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| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 18-May-2017   | 13561842                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1029036     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-May-2017   | 13561873                | EXPEDITED (15-DAY)        |                             | OT                       | NZ-MYLANLABS-2017M1029591     |                               |                          | Unknown             | NZL                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Use Issue  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-May-2017   | 13564778                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1028769     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Depressed Level Of Consciousness; Gait Disturbance; Loss Of Consciousness; Sensory Loss | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|   | Sprycel /05677301/      |                           |                             | C                        |                               | 100 Mg, Qd                    |                          | Mylan               |                         |
|   | Alprazolam              |                           |                             | C                        |                               | 2 Mg, Tid                     |                          | Mylan               |                         |
|   | Gabapentin              |                           |                             | C                        |                               | 300 Mg, Tid                   |                          | Mylan               |                         |
|   | Amitriptyline           |                           |                             | C                        |                               | 75 Mg, Qd                     |                          | Mylan               |                         |
|   | Tramadol                |                           |                             | C                        |                               | 50 Mg, Bid                    |                          | Mylan               |                         |
|   | Paxil /00830802/        |                           |                             | C                        |                               | 20 Mg, Qd                     |                          | Mylan               |                         |
|   | Cyanocobalamin          |                           |                             | C                        |                               | 1000 Mg, Monthly              |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-May-2017   | 13564850                | EXPEDITED (15-DAY)        |                             | LT                       | NL-MYLANLABS-2017M1030159     |                               |                          | Unknown             | NLD                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|  |                         |                           |                             |                          |                               |                               |                          |                     |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Needle Issue               |                         | Epipen                    | S                           |                          | 0.3 Mg, Unk                   |                               | Mylan                    |                     |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-May-2017                                | 13565183                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1029029     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission         | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-May-2017                                | 13565187                | EXPEDITED (15-DAY)        |                             | LT                       | NL-MYLANLABS-2017M1030429     |                               |                          | Unknown             | NLD                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Needle Issue               | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-May-2017                                | 13567403                | NON-EXPEDITED             |                             | LT, OT                   | US-PFIZER INC-2017222170      |                               | 71 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                           | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-May-2017                                | 13568649                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1029448     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Intentional Product Misuse | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-May-2017                                | 13569153                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017222171      |                               | 16 YR                    | Male                | USA                     |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective  | Epipen Jr            |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-May-2017   | 13569491             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017224417  |                      | 37 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Depressed Level Of Consciousness; Gait Disturbance; Loss Of Consciousness; Sensory Loss | Epipen 0.3mg         |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
|   | Sprycel /05677301/   |                    |                    | C               |                           | 100 Mg, Qd           |                 |            |                |
|   | Alprazolam           |                    |                    | C               |                           | 2 Mg, Tid            |                 |            |                |
|   | Gabapentin           |                    |                    | C               |                           | 300 Mg, Tid          |                 |            |                |
|   | Amitriptyline        |                    |                    | C               |                           | 75 Mg, Qd            |                 |            |                |
|   | Tramadol             |                    |                    | C               |                           | 50 Mg, Bid           |                 |            |                |
|   | Paxil /00830802/     |                    |                    | C               |                           | 20 Mg, Qd            |                 |            |                |
|   | Cyanocobalamin       |                    |                    | C               |                           | 1000 Mg, Monthly     |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-May-2017   | 13569600             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-MYLANLABS-2017M1029296 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-May-2017   | 13578054             | EXPEDITED (15-DAY) |                    | LT              | NZ-MYLANLABS-2017M1030454 |                      |                 | Unknown    | NZL            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission                                    | Epipen Junior        |                    |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |



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| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|--|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 25-May-2017   | 13579450                                   | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1029514     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen Auto-Injector                       |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-May-2017   | 13580865                                   | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2017M1023538     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Issue; Drug Dose Omission; Needle Issue; Product Quality Issue | Epipen                                     |                           |                             | S                        |                               | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 25-May-2017   | 13596660                                   | DIRECT                    |                             | HO, OT                   |                               |                               | 16 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; Product Quality Issue; Product Use Issue                                | Epipen 2pak Auto Injectors.3mg<br>Benadryl |                           |                             | S<br>C                   | Intramuscular                 | Quantity:1 Injection(S);      |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-May-2017   | 13586556                                   | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1030002     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                    | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Auto-Injector                       |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                     | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-May-2017   | 13586872                                   | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1030901     |                               |                          | Unknown             | USA                     |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|--|-------------------------------|--------------------------|---------------------|-------------------------|
| Drug Ineffective  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                                  | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-May-2017   | 13591316                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017233330                       |                               | 52 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen                  |                           |                             | S                        | Intramuscular                                  | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-May-2017   | 13592367                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017235617                       |                               | 58 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Urticaria   | Epipen 0.3mg            |                           |                             | S                        | Intramuscular                                  | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 01-Jun-2017   | 13602039                | NON-EXPEDITED             |                             | OT                       | US-ARBOR PHARMACEUTICALS, LLC-US-2016ARB000549 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Anxiety; Depression; Headache; Hypersensitivity; Insomnia; Off Label Use; Panic Attack; Suicidal Ideation; Urinary Incontinence | Gabapentin Enacarbil    |                           |                             | S                        | Oral   | 300 Mg, Qd, 300 Mg, Daily     |                          | Arbor               |                         |
|   | Hydrochlorothiazide     |                           |                             | C                        |  |                               |                          |                     |                         |
|   | Benadryl /00000402/     |                           |                             | C                        |  | As Needed                     |                          |                     |                         |
|   | Epi E-Z Pen Jr.         |                           |                             | S                        |  |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a>                  | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Jun-2017   | 13568634                | EXPEDITED (15-DAY)        |                             | HO                       | US-PFIZER INC-2017217541                       |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>                          | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|  |                      |                    |                    |                 |                           |                      |                 |            |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Contraindicated Product Administered; Throat Tightness                       |                      | Epipen             |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Jun-2017  | 13605945             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017235845  |                      | 19 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Discomfort; Chest Pain; Drug Ineffective                           | Epipen Jr            |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
|  | Benadryl             |                    |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Jun-2017  | 13609317             | EXPEDITED (15-DAY) |                    | HO              | JP-MYLANLABS-2017M1033274 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Palpitations; Product Use In Unapproved Indication | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Jun-2017  | 13609457             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-MYLANLABS-2017M1032051 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered                               | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|  | Zoloft               |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|  | Estrogen             |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2017  | 13615350             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017245242  |                      | 46 YR           | Female     | USA            |

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| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Drug Effect Decreased; Expired Product Administered; Headache                             | Epipen         |                    |                    | S               | Intramuscular            | 0.3 Mg, Prn          |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Jun-2017   | 13615672       | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2017243123 |                      | 35 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired Product Administered  | Epipen Jr      |                    |                    | S               | Intramuscular            | 0.3 Mg, Once         |                 | Pfizer     |                |
|   | Zoloft         |                    |                    | C               |                          | Unk                  |                 |            |                |
|   | Estrogen       |                    |                    | C               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Jun-2017   | 13586156       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017233352 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Heart Rate Increased; Injection Site Haemorrhage | Epipen 0.3mg   |                    |                    | S               |                          | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Jun-2017   | 13602397       | EXPEDITED (15-DAY) |                    | HO              | JP-PFIZER INC-2017232453 |                      | 64 YR           | Female     | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Palpitations; Product Use In Unapproved Indication              | Epipen 0.3mg   |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen 0.3mg   |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen 0.3mg   |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen 0.3mg   |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 09-Jun-2017   | 13636209                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1032867 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Jun-2017   | 13636273                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1033446 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jun-2017   | 13616309                 | EXPEDITED (15-DAY) |                    | LT              | BE-MYLANLABS-2017M1033516 |                      |                 | Unknown    | BEL            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 1 Df, Total          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jun-2017   | 13642699                 | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1034282 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission; Injection Site Laceration; Needle Issue | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jun-2017   | 13643209                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1034277 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|   |                          |                    |                    |                 |                           |                      |                 |            |                |

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|  |                      |                    |                    |                 |                           |                      |                    |                 |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| Device Failure   | Epipen Auto-Injector |                    | S                  |                 | Unk                       |                      |                    | Mylan           |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 12-Jun-2017  | 13644245             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017255280  |                      | 14 YR              | Male            | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective   | Epipen               |                    |                    | S               |                           | Intramuscular        | 0.3 Mg, Prn        |                 | Pfizer         |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 14-Jun-2017  | 13650143             | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2017257652  |                      |                    | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective   | Epipen               |                    |                    | S               |                           |                      | Unk                |                 | Pfizer         |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 14-Jun-2017  | 13650604             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017255399  |                      | 10 YR              | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Device Failure; Device Use Issue; Injection Site Erythema; Product Quality Issue | Epipen               |                    |                    | S               |                           | Intramuscular        | 0.3 Mg, Once       |                 | Pfizer         |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 14-Jun-2017  | 13650694             | EXPEDITED (15-DAY) |                    | HO, OT          | JP-MYLANLABS-2017M1035537 |                      |                    | Unknown         | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Hospitalisation  | Epipen               |                    |                    | S               |                           |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 15-Jun-2017  | 13402572             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1020604 |                      |                    | Unknown         | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------|-----------------|------------|----------------|
| Device Failure; Dyspnoea;<br>Injection Site Bruising;<br>Injection Site<br>Haemorrhage          | Epipen Auto-Injector |                    |                    | S               |                           | Unk                       |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                       |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Jun-2017   | 13418864             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2017M1021195 |                           |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure;<br>Hypertension; Migraine   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once              |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Jun-2017   | 13654761             | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2017M1034886 |                           |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               |                           |                           |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jun-2017   | 13444812             | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2017160759  |                           | 31 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Arrhythmia; Blood<br>Pressure Increased;<br>Product Use Issue;<br>Regurgitation;<br>Tachycardia | Epipen               |                    |                    | S               |                           | 0.3 Mg, Unk [Upper Thigh] |                 | Pfizer     |                |
|   | Lyrica               |                    |                    | C               |                           | 225 Mg, 2x/Day            |                 |            |                |
|   | Dimetapp             |                    |                    | C               |                           | Unk                       |                 |            |                |
|   | Omeprazole           |                    |                    | C               |                           | Unk                       |                 |            |                |
|   | Nexium               |                    |                    | C               |                           | Unk                       |                 |            |                |
|   | Depo Provera         |                    |                    | C               |                           | Unk                       |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Jun-2017   | 13659476             | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2017M1034865 |                           |                 | Unknown    | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Drug Dose Omission; Keloid Scar                                      | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Jun-2017  | 13659486                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1034244     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Jun-2017  | 13661187                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017264557      |                               | 10 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child; Injury Associated With Device; Needle Issue | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Jun-2017  | 13661193                | NON-EXPEDITED             |                             | HO                       | US-PFIZER INC-2017264326      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue          | Epipen Jr               |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Jun-2017  | 13661270                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017265214      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Effect Delayed  | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |



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| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|-------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 16-Jun-2017   | 13661643                | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1034871 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector    |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|   | Epipen Auto-Injector    |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Jun-2017   | 13663509                | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017264558  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Expired Product Administered; Palpitations | Epipen 0.3mg            |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Jun-2017   | 13675439                | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1035679 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Discolouration; Injection Site Swelling              | Epipen Auto-Injector    |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Loratadine              |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|   | Multivitamin /00097801/ |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|   | Norvasc                 |                    |                    | C               |                           |                      |                 | Mylan      |                |
|   | Atenolol                |                    |                    | C               |                           |                      |                 | Mylan      |                |
|   | Estrace                 |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2017   | 13434334                | NON-EXPEDITED      |                    | HO, OT          | US-PFIZER INC-2017153372  |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                          |                    |                    |                 |                          |                      |                 |            |                |
|--|--------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Device Use Issue; Hypertension; Migraine; Product Quality Issue            |                          |                    |                    |                 |                          |                      |                 |            |                |
| Epipen 0.3mg   |                          | S                  |                    | Intramuscular   |                          | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2017  | 13679764                 | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-PFIZER INC-2017268344 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue; Renal Failure | Epipen                   |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jun-2017  | 13681931                 | DIRECT             | Y                  | DS              |                          |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Overdose; Brain Injury  | Simvastatin 20mg Tablet  |                    |                    | S               |                          |                      |                 |            |                |
|  | Alprazolam 0.25mg        |                    |                    | S               |                          |                      |                 |            |                |
|  | Olanzapine 15mg          |                    |                    | S               |                          |                      |                 |            |                |
|  | Aripiprazole 10 Mg       |                    |                    | S               |                          |                      |                 |            |                |
|  | Escitalopram 20mg        |                    |                    | S               |                          |                      |                 |            |                |
|  | Lantus                   |                    |                    | S               |                          |                      |                 |            |                |
|  | Metformin                |                    |                    | S               |                          |                      |                 |            |                |
|  | Meloxicam 15mg           |                    |                    | S               |                          |                      |                 |            |                |
|  | Omeprazole 20mg          |                    |                    | S               |                          |                      |                 |            |                |
|  | Toviaz Er                |                    |                    | S               |                          |                      |                 |            |                |
|  | Divalproex Sod           |                    |                    | S               |                          |                      |                 |            |                |
|  | Propranolol 40mg Tab Her |                    |                    | S               |                          |                      |                 |            |                |
|  | Ibuprofen                |                    |                    | S               |                          |                      |                 |            |                |
|  | Ventolin Hfa             |                    |                    | S               |                          |                      |                 |            |                |
|  | Epipen                   |                    |                    | S               |                          |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jun-2017  | 13438816                 | EXPEDITED (15-DAY) |                    | LT, OT          | JP-PFIZER INC-2017111622 |                      | 18 YR           | Male       | JPN            |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Dyspnoea  | Epipen 0.3mg            |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jun-2017   | 13648470                | NON-EXPEDITED             |                             | LT, OT                   | US-PFIZER INC-2017255312      |                               | 36 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jun-2017   | 13664711                | EXPEDITED (15-DAY)        |                             | OT                       | CH-MYLANLABS-2017M1036216     |                               |                          | Unknown             | CHE                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Expired Product Administered                                | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 23-Jun-2017   | 13689341                | DIRECT                    |                             | RI                       |                               |                               | 7 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Reaction; Laceration; Needle Issue                           | Epi Pen Jr Claritin     |                           |                             | S<br>C                   |                               |                               |                          |                     |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 24-Jun-2017   | 13518883                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1026367     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | Unk Unk, Prn                  |                          | Mylan               |                         |
|   | Asa                     |                           |                             | C                        | Oral                          | 4 Df, Qd                      |                          | Mylan               |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 24-Jun-2017   | 13586194       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1031587 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Needle Issue; Product Quality Issue           | Epipen         |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
|   | Epipen         |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
|   | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Jun-2017   | 13330491       | EXPEDITED (15-DAY) |                    | OT              | CH-MYLANLABS-2017M1015181 |                      |                 | Unknown    | CHE            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Wrong Technique In Device Usage Process                         | Epipen Jr      |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jun-2017   | 13693792       | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2017277345  |                      | 61 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Ineffective; Needle Issue                | Epipen         |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Jun-2017   | 13675295       | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2017264459  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Effect Incomplete; Product Quality Issue | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|   | Epipen         |                    |                    | S               |                           |                      |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 29-Jun-2017  | 13655721             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017260581  |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jun-2017  | 13656318             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017261588  |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Injection Site Laceration; Needle Issue; Product Quality Issue                   | Epipen Jr            |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jun-2017  | 13703234             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1037099 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Discomfort; Device Failure; Expired Product Administered   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|  | Lisinopril           |                    |                    | C               | Oral                      | 20 Mg, Qam           |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2017  | 13427904             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017149067  |                      | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Dyspnoea; Expired Product Administered; Injection Site Bruising; Injection Site Haemorrhage; Product | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|  | Benadryl             |                    |                    | C               |                           | Unk                  |                 |            |                |

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|   |                            |                    |                    |                 |                          |                           |                 |            |                |
|---|----------------------------|--------------------|--------------------|-----------------|--------------------------|---------------------------|-----------------|------------|----------------|
| Quality Issue   |                            |                    |                    |                 |                          |                           |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2017   | 13674760                   | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017264328 |                           |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen                     |                    |                    | S               |                          | Unk                       |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2017   | 13675294                   | NON-EXPEDITED      |                    | HO              | US-PFIZER INC-2017264460 |                           |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue                                 | Epipen                     |                    |                    | S               |                          | Unk                       |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2017   | 13685372                   | EXPEDITED (15-DAY) |                    | DE, OT          | US-PFIZER INC-2017275046 |                           |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Death   | Epipen                     |                    |                    | S               |                          | Unk                       |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jun-2017   | 13707431                   | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017285003 |                           | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Discomfort; Device Failure; Device Use Issue; Expired Product Administered; Product Quality Issue | Epipen 0.3mg<br>Lisinopril |                    |                    | S<br>C          | Intramuscular<br>Oral    | 0.3 Mg, Prn<br>20 Mg, Qam |                 | Pfizer     |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 30-Jun-2017   | 13708467             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1038230 |   |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered                          | Epipen Auto-Injector |                    |                    | S               |                           | Unk   |                 | Mylan      |                |
|   | Wellbutrin           |                    |                    | C               |                           | 150 Mg, Qd                                  |                 | Mylan      |                |
|   | Vyvanse              |                    |                    | C               |                           | 20 Mg, Qd                                   |                 | Mylan      |                |
|   | Ephedrine            |                    |                    | C               |                           | Unk, Prn                                    |                 | Mylan      |                |
|   | Benadryl /00000402/  |                    |                    | C               |                           | Unk, Prn                                    |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Jul-2017   | 13361266             | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1018050 |   |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Needle Issue; Product Quality Issue | Epipen               |                    |                    | S               |                           | 0.3 Mg, Unk                                 |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Jul-2017   | 13711409             | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2017M1039737 |   |                 | Unknown    | FRA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u> |                |
| Hyperhidrosis; Hypertension; Malaise; Pallor; Tachycardia; Tremor     | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Daily Dose: 0.3 Mg Milligram(S) Every Total |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                        | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Jul-2017   | 13719362             | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2017292499  |   | 27 YR           | Male       | FRA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                          | <u>Duration</u> | <u>Mfr</u> |                |

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|   |                         |                           |                             |                          |                               |                       |                               |   |                     |                         |  |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-----------------------|-------------------------------|---|---------------------|-------------------------|--|
| Accidental Exposure To Product; Hyperhidrosis; Hypertension; Malaise; Pallor; Tachycardia; Tremor |                         |                           | Epipen 0.3mg                |                          | S                             | Intramuscular         |                               | Daily Dose: 0.3 Mg Milligram(S) Every Total |                     | Pfizer                  |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>                         | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 06-Jul-2017   | 13722130                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017285325      |                       |                               | 59 YR                                       | Female              | USA                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a>                    | <a href="#">Mfr</a> |                         |  |
| Drug Ineffective  | Epipen                  |                           |                             |                          | S                             | Intramuscular         | 0.3 Mg, Once                  |   | Pfizer              |                         |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>                         | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 06-Jul-2017   | 13722159                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017285260      |                       |                               | 16 YR                                       | Male                | USA                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a>                    | <a href="#">Mfr</a> |                         |  |
| Drug Ineffective  | Epipen                  |                           |                             |                          | S                             |                       | Unk                           |   | Pfizer              |                         |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>                         | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 06-Jul-2017   | 13726506                | EXPEDITED (15-DAY)        |                             | OT                       | AU-MYLANLABS-2017M1039729     |                       |                               |   | Unknown             | AUS                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a>                    | <a href="#">Mfr</a> |                         |  |
| Drug Ineffective  | Epipen                  |                           |                             |                          | S                             |                       |                               |   | Mylan               |                         |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>                         | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 07-Jul-2017   | 13733686                | EXPEDITED (15-DAY)        |                             | HO, LT, OT               | US-MYLANLABS-2017M1039890     |                       |                               |   | Unknown             | USA                     |  |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a> | <a href="#">Dosage Text</a>   | <a href="#">Duration</a>                    | <a href="#">Mfr</a> |                         |  |
| Device Failure  | Epipen Auto-Injector    |                           |                             |                          | S                             |                       | Unk                           |   | Mylan               |                         |  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> |                       | <a href="#">503B Facility</a> | <a href="#">Age</a>                         | <a href="#">Sex</a> | <a href="#">Country</a> |  |
| 12-Jul-2017   | 13423504                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017151096      |                       |                               | 63 YR                                       | Female              | USA                     |  |



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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Drug Hypersensitivity;<br>Dyspnoea; Palpitations  | Epipen               |                    |                    | S               |                               | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2017   | 13591410             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-<br>2017201090  |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device<br>Use Issue; Drug Dose<br>Omission; Drug<br>Ineffective; Product<br>Quality Issue | Epipen               |                    |                    | S               | Intramuscular                 | 0.3 Mg, As Needed    |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               | Intramuscular                 | 0.3 Mg, Unk          |                 | Pfizer     |                |
|   | Asa                  |                    |                    | C               | Oral                          | 4 Df, Qd             |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2017   | 13745614             | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-<br>2017297771  |                      | 5 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pancreatitis Acute;<br>Rotavirus Infection  | Epipen Jr            |                    |                    | S               | Intramuscular                 | 0.15 Mg, Once        |                 | Pfizer     |                |
|   | Zofran /00955301/    |                    |                    | C               |                               | Unk                  |                 |            |                |
|   | Solumedrol           |                    |                    | C               |                               | Unk                  |                 |            |                |
|   | Benadryl             |                    |                    | C               |                               | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2017   | 13746516             | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-<br>2017M1042332 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction  | Epipen Auto-Injector |                    |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jul-2017   | 13746518             | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-<br>2017M1042334 |                      |                 | Unknown    | AUS            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Malfunction   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Jul-2017  | 13746519                | EXPEDITED (15-DAY)        |                             | OT                       | AU-MYLANLABS-2017M1042333     |                               |                          | Unknown             | AUS                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Malfunction   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Jul-2017  | 13747337                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1040205     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered; Injection Site Pain; Pain  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 13-Jul-2017  | 13749064                | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2017300137      |                               | 33 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered; Injection Site Pain; Pain  | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Jul-2017  | 13735359                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017287926      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Headache; Lethargy; Nausea; Product Quality Issue; Product Use | Epipen                  |                           |                             | S                        |                               | 0.3 Mg, Unk                   |                          | Pfizer              |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue; Vomiting

| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 17-Jul-2017                                   | 13758946                | EXPEDITED (15-DAY)        |                             | HO                       | JP-MYLANLABS-2017M1043064     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hospitalisation                               | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Jul-2017                                   | 13760729                | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2017M1041571     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Effect Incomplete                        | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Jul-2017                                   | 13761501                | EXPEDITED (15-DAY)        |                             | OT                       | AU-MYLANLABS-2017M1042709     |                               |                          | Unknown             | AUS                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Breakage; Device Issue; Device Leakage | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Jul-2017                                   | 13770413                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1041522     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                                | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>             | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Jul-2017                                   | 13507778                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017191898      |                               | 15 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|   |                      |                    |                    |                 |                           |                       |                 |            |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------|-----------------|------------|----------------|
| Injection Site Pain   |                      | Epipen             |                    | S               |                           | Unk                   |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Jul-2017   | 13775371             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2017M1026111 |                       | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective For Unapproved Indication; Injection Site Movement Impairment; Injection Site Pain | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once          |                 | Mylan      |                |
|   | Prednisone           |                    |                    | S               |                           | 5 Mg, Prn             |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jul-2017   | 13779878             | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2017M1043368 |                       |                 | Unknown    | ITA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen               |                    |                    | S               |                           | Unk                   |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Jul-2017   | 13779974             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1042172 |                       |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Jul-2017   | 13782048             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017317564  |                       | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Effect Incomplete; Product Quality Issue; Tremor             | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Single (Once) |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 24-Jul-2017  | 13782334      | DIRECT             | Y                  |                 |                           |                      |            | Unknown    | USA            |
| <div> <div><u>Preferred Term</u></div> <div>Accidental Exposure To Product; Product Label Issue</div> </div> <div> <div><u>Product</u></div> <div>Epipen Epinephrine</div> </div> <div> <div><u>Comp.</u></div> <div></div> </div> <div> <div><u>OTC</u></div> <div></div> </div> <div> <div><u>Role</u></div> <div>S</div> </div> <div> <div><u>Route</u></div> <div></div> </div> <div> <div><u>Dosage Text</u></div> <div></div> </div> <div> <div><u>Duration</u></div> <div></div> </div> <div> <div><u>Mfr</u></div> <div></div> </div>                      |               |                    |                    |                 |                           |                      |            |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 24-Jul-2017  | 13782761      | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1042606 |                      |            | Unknown    | USA            |
| <div> <div><u>Preferred Term</u></div> <div>Device Failure; Drug Ineffective; Tremor</div> </div> <div> <div><u>Product</u></div> <div>Epipen Auto-Injector</div> </div> <div> <div><u>Comp.</u></div> <div></div> </div> <div> <div><u>OTC</u></div> <div></div> </div> <div> <div><u>Role</u></div> <div>S</div> </div> <div> <div><u>Route</u></div> <div>Intramuscular</div> </div> <div> <div><u>Dosage Text</u></div> <div>0.3 Mg, Once</div> </div> <div> <div><u>Duration</u></div> <div></div> </div> <div> <div><u>Mfr</u></div> <div>Mylan</div> </div> |               |                    |                    |                 |                           |                      |            |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 25-Jul-2017  | 13789954      | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017317632  |                      | 74 YR      | Male       | USA            |
| <div> <div><u>Preferred Term</u></div> <div>Drug Ineffective</div> </div> <div> <div><u>Product</u></div> <div>Epipen Jr<br/>Chloramphenicol</div> </div> <div> <div><u>Comp.</u></div> <div></div> </div> <div> <div><u>OTC</u></div> <div></div> </div> <div> <div><u>Role</u></div> <div>S<br/>C</div> </div> <div> <div><u>Route</u></div> <div>Intramuscular</div> </div> <div> <div><u>Dosage Text</u></div> <div>0.3 Mg, Prn<br/>Unk</div> </div> <div> <div><u>Duration</u></div> <div></div> </div> <div> <div><u>Mfr</u></div> <div>Pfizer</div> </div>  |               |                    |                    |                 |                           |                      |            |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
| 26-Jul-2017  | 13792953      | DIRECT             |                    | OT              |                           |                      | 8 YR       | Male       | USA            |
| <div> <div><u>Preferred Term</u></div> <div>Device Malfunction; Medical Device Site Pain; Needle Issue; Needle Issue</div> </div> <div> <div><u>Product</u></div> <div>Epipen Jr.</div> </div> <div> <div><u>Comp.</u></div> <div></div> </div> <div> <div><u>OTC</u></div> <div></div> </div> <div> <div><u>Role</u></div> <div>S</div> </div> <div> <div><u>Route</u></div> <div></div> </div> <div> <div><u>Dosage Text</u></div> <div></div> </div> <div> <div><u>Duration</u></div> <div></div> </div> <div> <div><u>Mfr</u></div> <div>Mylan</div> </div>    |               |                    |                    |                 |                           |                      |            |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 27-Jul-2017  | 13773200             | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-2017298652  |                      | 40 YR           | Female     | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Blood Pressure Increased; Heart Rate Increased; Palpitations | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 27-Jul-2017  | 13800805             | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2017M1043115 |                      |                 | Unknown    | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Leakage; Device Malfunction   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Jul-2017  | 13661681             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1034890 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
|  | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Jul-2017  | 13803068             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1043583 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Jul-2017  | 13803340             | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017319114  |                      |                 | Unknown    | USA            |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|---|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen                                    |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 29-Jul-2017   | 13711225                                  | EXPEDITED (15-DAY)        |                             | DE                       | GB-MYLANLABS-2017M1039167     |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen Auto-Injector                      |                           |                             | S                        | Intramuscular                 | 1 Df, Total                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 31-Jul-2017   | 13586555                                  | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1030019     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Contusion; Device Failure   | Epipen Auto-Injector                      |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 31-Jul-2017   | 13817603                                  | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017328254      |                               | 51 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injection Site Scar   | Epipen                                    |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 31-Jul-2017   | 13818646                                  | EXPEDITED (15-DAY)        |                             | OT                       | GB-MYLANLABS-2017M1045149     |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Device Failure                            | Epipen (Epinephrine) Auto Injector 0.3 Mg |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

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| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 01-Aug-2017   | 13821886                | NON-EXPEDITED             |                             | LT, OT                   | US-PFIZER INC-2017330125      |                               | 74 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Aug-2017   | 13824598                | DIRECT                    |                             | LT                       |                               |                               | 41 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Malfunction;<br>Product Quality Issue  | Epipen                  |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Aug-2017   | 13825964                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1045243     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Aug-2017   | 13827461                | EXPEDITED (15-DAY)        |                             | OT                       | FR-MYLANLABS-2017M1046458     |                               |                          | Unknown             | FRA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To<br>Product; Exposure During<br>Pregnancy; Injection Site<br>Discolouration; Wrong<br>Technique In Product<br>Usage Process | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Aug-2017   | 13733674                | EXPEDITED (15-DAY)        |                             | OT                       | GB-MYLANLABS-2017M1041012     |                               |                          | Unknown             | GBR                     |



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| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Drug Dose Omission; Needle Issue  | Epipen Jr               |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Aug-2017   | 13835216                | EXPEDITED (15-DAY)        |                             | OT                       | FR-PFIZER INC-2017337114      |                               |                          | Female              | FRA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injection Site Discolouration; Wrong Technique In Product Usage Process | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Aug-2017   | 13836263                | EXPEDITED (15-DAY)        |                             | OT                       | CA-PFIZER INC-2017338095      |                               | 30 YR                    | Female              | CAN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Abortion Spontaneous  | Epipen Jr               |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Unk                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Aug-2017   | 12841498                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2016M1043226     |                               |                          | Unknown             | CAN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen                  |                           |                             | S                        | Intramuscular                 |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 07-Aug-2017   | 13711418                | EXPEDITED (15-DAY)        |                             | OT                       | GB-MYLANLABS-2017M1039735     |                               |                          | Unknown             | GBR                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Effect Incomplete  | Epipen                  |                           |                             | S                        |                               | 0.3 Mg, Unk                   |                          | Mylan               |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 07-Aug-2017               | 13822132             | EXPEDITED (15-DAY) |                    | DE, LT, OT      | US-PFIZER INC-2017320598  |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthma; Brain Death;      | Epipen               |                    |                    | S               |                           | Two Epipens (2 Df)   |                 | Pfizer     |                |
| Cardiac Arrest; Drug      | Epipen               |                    |                    | S               |                           |                      |                 | Pfizer     |                |
| Ineffective;              |                      |                    |                    |                 |                           |                      |                 |            |                |
| Hypersensitivity; Hypoxia |                      |                    |                    |                 |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Aug-2017               | 13837911             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1046025 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased;    | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| Expired Product           |                      |                    |                    |                 |                           |                      |                 |            |                |
| Administered              |                      |                    |                    |                 |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Aug-2017               | 13841503             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017338093  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Decreased;    | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
| Expired Product           |                      |                    |                    |                 |                           |                      |                 |            |                |
| Administered              |                      |                    |                    |                 |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Aug-2017               | 13841509             | NON-EXPEDITED      |                    | HO, OT          | US-PFIZER INC-2017337809  |                      | 11 YR           | Male       | USA            |
| <u>Preferred Term</u>     | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective          | Epipen Jr            |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
|                           | Epipen Jr            |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
|                           | Benadryl             |                    |                    | C               | Sublingual                | 12.5 Mg, Single      |                 |            |                |

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|                                     |                          |                           |                             |                          |                               |                               |                             |                          |                         |
|-------------------------------------|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Benadryl                            |                          |                           | C                           |                          | Sublingual                    |                               | 12.5 Mg, Single             |                          |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 08-Aug-2017                         | 13818492                 | EXPEDITED (15-DAY)        |                             | OT                       | GB-MYLANLABS-2017M1046457     |                               |                             | Unknown                  | GBR                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Device Issue; Product Quality Issue | Epipen                   |                           |                             |                          | S                             |                               | Unk                         |                          | Mylan                   |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 08-Aug-2017                         | 13842600                 | EXPEDITED (15-DAY)        |                             | OT                       | FI-MYLANLABS-2017M1048465     |                               |                             | Unknown                  | FIN                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Device Malfunction; Needle Issue    | Epipen Jr                |                           |                             |                          | S                             |                               | Unk                         |                          | Mylan                   |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 08-Aug-2017                         | 13843913                 | EXPEDITED (15-DAY)        |                             | DE, OT                   | JP-PFIZER INC-2017338994      |                               | 56 YR                       | Male                     | JPN                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Death                               | Epipen 0.3mg             |                           |                             |                          | S                             |                               |                             |                          | Pfizer                  |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 08-Aug-2017                         | 13845317                 | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1046593     |                               |                             | Unknown                  | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Device Failure                      | Epipen Jr. Auto-Injector |                           |                             |                          | S                             | Intramuscular                 | 0.15 Mg, Once               |                          | Mylan                   |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 08-Aug-2017                         | 13846581                 | EXPEDITED (15-DAY)        |                             | HO, OT                   | US-MYLANLABS-2017M1047251     |                               |                             | Unknown                  | USA                     |
| <a href="#">Preferred Term</a>      | <a href="#">Product</a>  |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |

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|   |                      |                      |                    |                 |  |                      |                 |            |                |
|---|----------------------|----------------------|--------------------|-----------------|--|----------------------|-----------------|------------|----------------|
| Drug Ineffective  |                      | Epipen Auto-Injector |                    | S               | Intramuscular                              | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Aug-2017   | 13855852             | NON-EXPEDITED        |                    | DE, OT          | US-PFIZER INC-2017346856                   |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue   | Epipen               |                      |                    | S               |  | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Aug-2017   | 13857611             | EXPEDITED (15-DAY)   |                    | OT              | US-MYLANLABS-2017M1048708                  |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen Auto-Injector |                      |                    | S               | Intramuscular                              | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Aug-2017   | 13865206             | NON-EXPEDITED        |                    |                 | US-AEGERION PHARMACEUTICAL, INC-AEGR002779 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                               | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Allergy To Arthropod Sting; Dry Skin; Eczema; Erythema; Hyperhidrosis; Inappropriate Schedule Of Drug Administration; Peripheral Swelling; Rash; Skin Discolouration; Skin Exfoliation; Urticaria | Juxtapid             |                      |                    | S               | Oral                                       | 5 Mg, Qd             |                 | Aegerion   |                |
|   | Juxtapid             |                      |                    | S               | Oral                                       | 10 Mg, Qd            |                 | Aegerion   |                |
|   | Epipen               |                      |                    | S               |  | 1 Df, Single         |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                       | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Aug-2017   | 13866218             | EXPEDITED (15-DAY)   |                    | OT              | SE-MYLANLABS-2017M1049149                  |                      |                 | Unknown    | SWE            |

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| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|---|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| Device Failure   | Epipen 300 Míkrógrömm;<br>Stungulyf, Lausn í Áfylltum<br>Lyfjapenna |                    |                    | S               |                              | Unk, Prn             |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2017  | 13790189  | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-<br>2017316774 |                      | 13 YR           | Female     | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Injury  | Epipen 0.3mg  |                    |                    | S               | Intramuscular                | 0.3 Mg, Single       |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2017  | 13872316  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-<br>2017348617 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain  | Epipen  |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2017  | 13872360  | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-<br>2017350382 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device<br>Use Issue; Drug Dose<br>Omission; Product Quality<br>Issue | Epipen  |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Aug-2017  | 13872365  | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-<br>2017350297 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen  |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--|----------------------|-----------------|---------------------------------|----------------|
| 16-Aug-2017   | 13872741       | EXPEDITED (15-DAY) |                    | HO, OT          | RU-PFIZER INC-2017352847                           |                      |                 | Male                            | RUS            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Muscle Haemorrhage  | Epipen         |                    |                    | S               |  | Unk                  |                 | Pfizer                          |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 16-Aug-2017   | 13874092       | EXPEDITED (15-DAY) |                    | DE, OT          | JP-MYLANLABS-2017M1050035                          |                      |                 | Unknown                         | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Death   | Epipen         |                    |                    | S               |  | Unk                  |                 | Mylan                           |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 16-Aug-2017   | 13875107       | EXPEDITED (15-DAY) |                    | HO, OT          | RU-MYLANLABS-2017M1050084                          |                      |                 | Unknown                         | RUS            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Muscle Haemorrhage  | Epipen         |                    |                    | S               |  | Unk                  |                 | Mylan                           |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 18-Aug-2017   | 13883481       | EXPEDITED (15-DAY) |                    | OT              | AU-INTERNATIONAL MEDICATION SYSTEMS, LIMITED-20248 |                      | 9 YR            | Male                            | AUS            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Accidental Exposure To Product; Anxiety; Capillary Nail Refill Test Abnormal; Injection Site Haemorrhage; Injection Site Pain; Injection Site Swelling; Pain In Extremity; Pallor | Epipen Jr      |                    |                    | S               |  |                      |                 | International Medication System |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 24-Aug-2017  | 13903330             | EXPEDITED (15-DAY) |                    | HO, OT          | GB-MYLANLABS-2017M1043646 |                      |                 | Unknown    | GBR            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Administration Site Discolouration; Infection; Injection Site Reaction | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 25-Aug-2017  | 13866907             | EXPEDITED (15-DAY) |                    | HO, OT          | GB-PFIZER INC-2017314249  |                      | 23 YR           | Female     | GBR            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Administration Site Discolouration; Infection; Injection Site Reaction | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Aug-2017  | 13791818             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-MYLANLABS-2017M1044189 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission   | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Sep-2017  | 13845325             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1046601 |                      | 61 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|  | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 04-Sep-2017  | 13733659       | EXPEDITED (15-DAY) |                    | LT, OT          | FR-MYLANLABS-2017M1040666 |                      |                 | Unknown    | FRA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Complication Of Device Removal; Drug Ineffective; Needle Issue   | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Sep-2017  | 13937771       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017377521  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Bruising; Nervousness   | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2017  | 13941698       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017381988  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Coldness; Injection Site Hypoaesthesia  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Sep-2017  | 13942305       | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2017381957  |                      | 9 YR            | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection Site Coldness; Injection Site Ischaemia; Injection Site Pain; Injection Site Pallor; Injection Site | Epipen Jr      |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Pfizer     |                |



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|  |                                |                  |                    |                 |                                       |                      |                 |                 |                |
|--|--------------------------------|------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|-----------------|----------------|
| Paraesthesia   |                                |                  |                    |                 |                                       |                      |                 |                 |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 07-Sep-2017  | 13903276                       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017360522              |                      |                 | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Accidental Exposure To Product; Expired Product Administered; Vasodilatation   | Epipen Jr                      |                  |                    | S               |                                       | Unk                  |                 | Pfizer          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 11-Sep-2017  | 13922032                       | NON-EXPEDITED    |                    |                 | US-PFIZER INC-2017371089              |                      |                 | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Hypoaesthesia; Injection Site Paraesthesia; Injection Site Swelling; Wrong Technique In Product Usage Process | Epipen Jr                      |                  |                    | S               |                                       | Unk                  |                 | Pfizer          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                  | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>      | <u>Country</u> |
| 13-Sep-2017  | 13963315                       | NON-EXPEDITED    |                    |                 | US-GLAXOSMITHKLINE-US2017139403       |                      | 53 YR           | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                 | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>      |                |
| Anxiety; Dysphagia; Dyspnoea; Gait Disturbance; Hypersensitivity; Nausea; Nervousness; Pruritus; Tremor  | Benlysta Solution For Infusion |                  |                    | S               | Intravenous (not otherwise specified) | 720 Mg, Z            |                 | Glaxosmithkline |                |
|  | Epipen (Adrenalin)             |                  |                    | S               |                                       |                      |                 |                 |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 14-Sep-2017  | 13935905             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | HU-MYLANLABS-2017M1054142 |                      |                 | Female     | HUN            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Brain Injury; Coma; Drug Ineffective; Dyspnoea   | Epipen               |                    |                    | S               |                           | 2 Df, Unk            |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Sep-2017  | 13961546             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1056198 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Sep-2017  | 13973115             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1055528 |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|  | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 15-Sep-2017  | 13976261             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017401084  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Dizziness; Feeling Abnormal; Feeling Jittery; Palpitations | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Sep-2017  | 13036474             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | CA-MYLANLABS-2016M1055645 |                      | 8 YR            | Unknown    | CAN            |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Drug Dose Omission  | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Sep-2017   | 13983709                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017398550      |                               | 16 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Issue; Injection Site Haemorrhage; Needle Issue; Product Quality Issue; Product Storage Error  | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 19-Sep-2017   | 13988020                | EXPEDITED (15-DAY)        |                             | OT                       | US-MYLANLABS-2017M1056442     |                               | 56 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Sep-2017   | 13942401                | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2017378716      |                               | 1 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child; Conjunctival Hyperaemia; Eyelid Haematoma; Injury Corneal; Iris Injury; Lens Disorder; Mydriasis; Retinal Haemorrhage; Retinal Tear; Tachycardia | Epipen Jr               |                           |                             | S                        | Ophthalmic                    | Unk (1:1000 Of 0.15mg)        |                          | Pfizer              |                         |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 20-Sep-2017  | 13961144       | EXPEDITED (15-DAY) |                    | OT              | FI-PFIZER INC-2017389135  |                      | 68 YR           | Male       | FIN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Ineffective; Needle Issue | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2017  | 13963046       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017392378  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen 0.3mg   |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Pfizer     |                |
|  | Epipen 0.3mg   |                    |                    | S               |                           |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2017  | 13967368       | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017392447  |                      | 48 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective   | Epipen         |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Pfizer     |                |
|  | Epipen         |                    |                    | S               |                           |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Sep-2017  | 13994488       | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2017M1057373 |                      | 25 YR           | Female     | SWE            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Condition Aggravated;  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| Hypersensitivity; Incorrect Dose Administered;                   | Desloratadin   |                    |                    | C               |                           | 1 Piece              |                 | Mylan      |                |
| Needle Issue   | Desloratadin   |                    |                    | C               |                           |                      |                 | Mylan      |                |
|  | Desloratadin   |                    |                    | C               |                           |                      |                 | Mylan      |                |
|  | Betapred       |                    |                    | C               |                           | 10 Pieces            |                 | Mylan      |                |
|  | Betapred       |                    |                    | C               |                           |                      |                 | Mylan      |                |

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|  |                         |                           |                             |                          |                               |                               |                             |                          |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Betapred   |                         |                           | C                           |                          |                               |                               | Mylan                       |                          |                         |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 25-Sep-2017  | 14009895                | EXPEDITED (15-DAY)        |                             | LT, OT                   | CA-MYLANLABS-2017M1056910     |                               |                             | Female                   | CAN                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Device Failure; Product Storage Error              | Epipen                  |                           |                             |                          | S                             |                               | Unk                         |                          | Mylan                   |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 26-Sep-2017  | 14010885                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017412973      |                               |                             | Female                   | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Drug Ineffective; Expired Product Administered     | Epipen Jr               |                           |                             |                          | S                             | Intramuscular                 | Unk                         |                          | Pfizer                  |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 26-Sep-2017  | 14013936                | EXPEDITED (15-DAY)        |                             | LT, OT                   | US-MYLANLABS-2017M1058536     |                               | 43 YR                       | Female                   | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Device Failure                                     | Epipen Auto-Injector    |                           |                             |                          | S                             | Intramuscular                 | 0.3 Mg, Once                |                          | Mylan                   |
|  | Epipen Auto-Injector    |                           |                             |                          | S                             |                               |                             |                          | Mylan                   |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 28-Sep-2017  | 13497077                | EXPEDITED (15-DAY)        |                             | HO, OT                   | US-MYLANLABS-2017M1025125     |                               | 53 YR                       | Female                   | USA                     |
| <a href="#">Preferred Term</a>                     | <a href="#">Product</a> |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Drug Effect Incomplete; Injection Site Haemorrhage | Epipen Auto-Injector    |                           |                             |                          | S                             | Intramuscular                 | 0.3 Mg, Once                |                          | Mylan                   |
| <a href="#">FDA Received Date</a>                  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 28-Sep-2017  | 13927015                | EXPEDITED (15-DAY)        |                             | OT                       | FR-MYLANLABS-2017M1055256     |                               | 67 YR                       | Male                     | FRA                     |

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| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Anaphylactic Shock;<br>Device Failure; Drug Dose<br>Omission  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Crestor        |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|   | Pariet         |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Oct-2017   | 13400517       | EXPEDITED (15-DAY) |                    | HO, OT          | JP-MYLANLABS-2017M1019839 |                      | 16 YR           | Male       | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device<br>Use Issue; Needle Issue   | Epipen         |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Oct-2017   | 14031416       | EXPEDITED (15-DAY) |                    | LT, OT          | CA-MYLANLABS-2017M1048722 |                      | 42 YR           | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Oct-2017   | 14017274       | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2017385274  |                      | 67 YR           | Male       | FRA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock;<br>Device Failure; Device<br>Use Issue; Drug Dose<br>Omission; Product Quality<br>Issue | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|   | Crestor        |                    |                    | C               |                           | Unk                  |                 |            |                |
|   | Pariet         |                    |                    | C               |                           | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Oct-2017   | 14035216       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017423205  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                               |                    |                    |                 |                          |                      |                 |            |                |
|---|-------------------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product By Child; Anxiety; Expired Product Administered; Flushing              |                               |                    |                    |                 |                          |                      |                 |            |                |
| Epipen Jr   |                               | S                  |                    | Intramuscular   |                          | 0.15 Mg, Prn         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Oct-2017   | 13650995                      | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-2017258315 |                      | 31 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Asthma; Device Failure; Device Use Issue; Drug Dose Omission; Hypersensitivity; Product Quality Issue | Epipen                        |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Epipen                        |                    |                    | S               |                          |                      |                 | Pfizer     |                |
|   | Salbutamol Sulfate            |                    |                    | C               |                          | Unk                  |                 |            |                |
|   | Breo Ellipta                  |                    |                    | C               |                          | Unk                  |                 |            |                |
|   | Diphenhydramine Hydrochloride |                    |                    | C               |                          | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Oct-2017   | 13984402                      | EXPEDITED (15-DAY) |                    | HO, LT, OT      | GB-PFIZER INC-2017366025 |                      |                 | Female     | HUN            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Brain Injury; Coma; Drug Ineffective; Dyspnoea  | Epipen                        |                    |                    | S               |                          | Two Doses            |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Oct-2017   | 14047732                      | EXPEDITED (15-DAY) |                    | LT, OT          | CA-PFIZER INC-2017083336 |                      | 42 YR           | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Issue; Product Quality Issue; Underdose  | Epipen                        |                    |                    | S               |                          | 0.3 Mg, As Needed    |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                 | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Oct-2017   | 14057745                      | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2017408624 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>                | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|  |                      |                    |                    |                 |                           |                      |                    |                 |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|--------------------|-----------------|----------------|
| Device Failure; Device Use Issue; Drug Dose Omission; Feeling Jittery; Needle Issue; Product Quality Issue | Epipen               |                    | S                  |                 |                           |                      | 0.3 Mg, Unk        |                 | Pfizer         |
|  | Epipen               |                    | S                  |                 |                           |                      | 0.3 Mg, Unk        |                 | Pfizer         |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 08-Oct-2017  | 14061162             | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1062908 |                      | 20 YR              | Male            | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Effect Incomplete   | Epipen               |                    |                    |                 | S                         |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 10-Oct-2017  | 13708762             | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2017285588  |                      | 42 YR              | Male            | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue                                  | Epipen               |                    |                    |                 | S                         | Intramuscular        | 0.3 Mg, Once       |                 | Pfizer         |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 10-Oct-2017  | 14075607             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2016M1059069 |                      |                    | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Device Failure   | Epipen Auto-Injector |                    |                    |                 | S                         |                      | Unk                |                 | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>         | <u>Sex</u>      | <u>Country</u> |
| 10-Oct-2017  | 14075644             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1001198 |                      | 54 YR              | Female          | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       |                    | <u>Comp.</u>       | <u>OTC</u>      | <u>Role</u>               | <u>Route</u>         | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u>     |
| Drug Ineffective   | Epipen Auto-Injector |                    |                    |                 | S                         | Intramuscular        | 0.3 Mg, Qd         |                 | Mylan          |
|  | Prednisone           |                    |                    |                 | C                         |                      | 90 Mg, Qd          |                 | Mylan          |



# FDA Adverse Event Reporting System

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| Hydroxyzine   |                          |                    | C                  |                 |                           | Unk                  |                 |            | Mylan          |  |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|--|
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 10-Oct-2017   | 14075675                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2016M1057817 |                      |                 | Female     | USA            |  |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure; Drug Dose Omission                                    | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |  |
|   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |  |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 10-Oct-2017   | 14075688                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2016M1059372 |                      | 3 YR            | Female     | USA            |  |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Accidental Exposure To Product By Child; Expired Product Administered | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |  |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 10-Oct-2017   | 14075716                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2016M1059468 |                      | 19 YR           | Male       | USA            |  |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure; Drug Dose Omission                                    | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |  |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 10-Oct-2017   | 14075755                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2016M1059045 |                      |                 | Male       | USA            |  |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure  | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Once        |                 | Mylan      |                |  |
|   | Epipen Jr. Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |  |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 10-Oct-2017  | 14075781                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2016M1058050 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission; Intentional Product Misuse                         | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Oct-2017  | 14075817                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1008237 |                      | 84 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Oct-2017  | 14075818                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1003317 |                      | 64 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Expired Product Administered; Feeling Jittery | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Oct-2017  | 14075916                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1005913 |                      | 1 YR            | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Off Label Use  | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Oct-2017  | 14076011                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1008728 |                      |                 | Female     | USA            |

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| <a href="#">Preferred Term</a> | <a href="#">Product</a>  | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|--------------------------------|--------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure                 | Epipen Jr. Auto-Injector |                       |                     | S                    | Intramuscular         | 0.15 Mg, Prn                |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Oct-2017                       | 14076043               | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1013114     |                               |                     | Male                | USA                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Circumstance Or Information Capable Of Leading To Medication Error; Product Quality Issue | Epipen Auto-Injector    |                       |                     | S                    |                       | Unk                         |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Oct-2017                       | 14076046               | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1011971     |                               | 64 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---------------------------------|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Device Failure; Product Leakage | Epipen Auto-Injector    |                       |                     | S                    |                       | Unk                         |                          | Mylan               |

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a> | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a> | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|---------------------|---------------------|-------------------------|
| 10-Oct-2017                       | 14076061               | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1013324     |                               | 71 YR               | Female              | USA                     |

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a> | <a href="#">OTC</a> | <a href="#">Role</a> | <a href="#">Route</a> | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a> |
|---|-------------------------|-----------------------|---------------------|----------------------|-----------------------|-----------------------------|--------------------------|---------------------|
| Feeling Jittery; Nervousness; Wrong Technique In Device Usage Process | Epipen Auto-Injector    |                       |                     | S                    | Intramuscular         | 0.3 Mg, Prn                 |                          | Mylan               |
|   | Epipen Auto-Injector    |                       |                     | S                    |                       |                             |                          | Mylan               |
|   | Zyrtec                  |                       |                     | C                    |                       | Unk                         |                          | Mylan               |
|   | Levocetirizine          |                       |                     | C                    |                       | Unk                         |                          | Mylan               |
|   | Hydroxyzine             |                       |                     | C                    |                       | Unk                         |                          | Mylan               |
|   | Hydroxyzine             |                       |                     | C                    |                       |                             |                          | Mylan               |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 10-Oct-2017   | 14076064             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1008707 |                      | 53 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Oct-2017   | 14076158             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1011663 |                      | 50 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Oct-2017   | 14076199             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1003613 |                      | 16 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Chest Pain; Disturbance In Attention; Expired Product Administered; Feeling Jittery; Headache; Injection Site Bruising; Injection Site Pain | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Oct-2017   | 14076633             | EXPEDITED (15-DAY) |                    | DE              | US-MYLANLABS-2011S1018679 |                      | 20 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock; Drug  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | .3 Mg, Once          |                 | Mylan      |                |

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| Effect Incomplete  | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 |            | Mylan          |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
|  | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 |            | Mylan          |
|  | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 |            | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 13499871             | NON-EXPEDITED      |                    | HO, OT          | US-PFIZER INC-2017189896  |                      | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Incomplete; Injection Site Haemorrhage   | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 13565227             | EXPEDITED (15-DAY) |                    | OT              | FR-MYLANLABS-2017M1030161 |                      | 55 YR           | Female     | FRA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Haematoma; Vasoconstriction   | Epipen               |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14077955             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1013915 |                      | 81 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Bruising; Injection Site Pain | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Coumadin /00014802/  |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14077967             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1014125 |                      | 9 YR            | Male       | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure; Needle Issue   | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017  | 14078055                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1015426     |                               | 3 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child; No Adverse Event; Product Quality Issue | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017  | 14078131                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1018702     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017  | 14078140                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1020766     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product   | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | Unk Mg, Unk                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017  | 14078154                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1020779     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017  | 14078179                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1020600 |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission; Injection Site Bruising; Injection Site Laceration; Needle Issue | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14078180                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1020892 |                      | 12 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|  | Zyrtec                   |                    |                    | C               | Oral                      | Unk, Monthly         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14078232                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1019815 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered   | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14078239                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1020608 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14078689                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-             |                      | 67 YR           | Male       | USA            |

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2017M1021535

| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Malaise; Vomiting                  | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|                                    | Lisinopril           |                    |                    | C               |                           | 20 Mg, Qd            |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14078707             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1023865 |                      | 67 YR           | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue       | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14078722             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1023882 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission | Epipen Auto-Injector |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14078723             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1022848 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                     | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14078725             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1021193 |                      | 55 YR           | Male       | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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|   |                          |                           |                             |                          |                               |                               |                          |                     |                         |
|---|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Drug Ineffective; Expired Product Administered; Product Storage Error |                          | Epipen Auto-Injector      |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078728                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1022892     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078742                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1023894     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Malaise   | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078769                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1023907     |                               | 21 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Effect Incomplete                                | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
|   | Rifabutin                |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |
|   | Xarelto                  |                           |                             | C                        |                               | 20 Mg, Qd                     |                          | Mylan               |                         |
|   | Trileptal                |                           |                             | C                        |                               | 100 Mg, Bid                   |                          | Mylan               |                         |
|   | Cipro /00697201/         |                           |                             | C                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                     | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078776                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1023916     |                               | 8 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017   | 14078778             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1023441 |                      | 54 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Back Disorder; Device Failure; Injection Site Haemorrhage | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078891             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1024505 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission; Rash  | Epipen Auto-Injector |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078920             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1025733 |                      | 75 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078922             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1025451 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078925             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1023901 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                          |                    |                    |                 |                           |                      |                 |            |                |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Expired Product Administered | Epipen Auto-Injector     | S                  | Intramuscular      | 0.3 Mg, Prn     |                           |                      |                 | Mylan      |                |
|  | Epipen Auto-Injector     | S                  |                    |                 |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                                  | 14078932                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1026100 |                      | 87 YR           | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                               | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 |            | Mylan          |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                                  | 14078936                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1024337 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission           | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 |            | Mylan          |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                                  | 14078945                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1025765 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Use Error; No Adverse Event           | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 |            | Mylan          |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                                  | 14078949                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1025083 |                      | 31 YR           | Female     | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                               | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 |            | Mylan          |
| <u>FDA Received Date</u>                     | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                                  | 14078953                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1025116 |                      | 45 YR           | Female     | USA            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product; Device Failure; Injection Site Discolouration; Injection Site Hypoaesthesia | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | Unk Unk, Once                 |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078954                | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1025380     |                               | 68 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
|   | Epipen Auto-Injector    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078955                | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1021197     |                               | 14 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078962                | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1024298     |                               | 39 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective  | Epipen Auto-Injector    |                           |                             | S                        |                               | 0.3 Mg, Once                  |                          | Mylan               |                         |
|   | Benadryl /00000402/     |                           |                             | S                        |                               | 1 Df, Once                    |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017   | 14078964                | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-2017M1023509     |                               | 48 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                          |                    |                          |                     |                           |                      |                 |            |                |
|---|--------------------------|--------------------|--------------------------|---------------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Injection Site Pain                           | Epipen Auto-Injector     | S                  | Intramuscular            | Unk Unk, Once       | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u>       | <u>Outcomes</u>     | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078965                 | EXPEDITED (15-DAY) |                          |                     | US-MYLANLABS-2017M1024300 |                      | 56 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>               | <u>Role</u>         | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector     | S                  | Intramuscular            | Unk Unk, Once       | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u>       | <u>Outcomes</u>     | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078967                 | EXPEDITED (15-DAY) |                          |                     | US-MYLANLABS-2017M1026383 |                      | 40 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>               | <u>Role</u>         | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Needle Issue                                  | Epipen Auto-Injector     | S                  | Intramuscular            | 0.3 Mg, Prn         | Mylan                     |                      |                 |            |                |
|   | Ritalin                  | C                  | Oral                     | 20 Mg, Tid          | Mylan                     |                      |                 |            |                |
|   | Claritin /00413701/      | C                  | Oral                     | 10 Mg, Qd           | Mylan                     |                      |                 |            |                |
|   | Pulmicort                | C                  | Respiratory (inhalation) | 90 Mg, 2 Puffs, Bid | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u>       | <u>Outcomes</u>     | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078979                 | EXPEDITED (15-DAY) |                          |                     | US-MYLANLABS-2017M1024295 |                      | 7 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>               | <u>Role</u>         | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Laceration; Needle Issue; Scar | Epipen Jr. Auto-Injector | S                  | Intramuscular            | 0.15 Mg, Once       | Mylan                     |                      |                 |            |                |
| <u>FDA Received Date</u>                                      | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u>       | <u>Outcomes</u>     | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14078988                 | EXPEDITED (15-DAY) |                          |                     | US-MYLANLABS-2017M1025472 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>               | <u>Role</u>         | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection                                     | Epipen Auto-Injector     | S                  | Intramuscular            | 0.3 Mg, Prn         | Mylan                     |                      |                 |            |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

|  |                      |                    |                    |                 |                           |                      |                 |            |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Site Bruising  | Epipen Auto-Injector |                    | S                  |                 |                           |                      |                 |            | Mylan          |
|  | Plavix               |                    | C                  |                 |                           | 75 Mg, Qd            |                 |            | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14078998             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1024333 |                      | 75 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; No Adverse Event   | Epipen Auto-Injector |                    |                    | S               |                           | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14078999             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1026092 |                      | 13 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Bruising; Injection Site Injury | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14079002             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1023939 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14079004             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1023915 |                      | 59 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Bruising  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
|  | Prozac               |                    |                    | C               |                           | Unk, Qd              |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                   |   |                                      |       |
|-------------------|---|--------------------------------------|-------|
| Bustar            | C | Unk, Tid                             | Mylan |
| Lasix /00032601/  | C | Unk, Qd                              | Mylan |
| Ambien            | C | Unk, Hs                              | Mylan |
| Zyrtec            | C | Unk, Qd                              | Mylan |
| Novolog           | C | 5 lu, Tid                            | Mylan |
| Albuterol Sulfate | C | Respiratory (inhalation)<br>Unk, Prn | Mylan |

| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017  | 14080046             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1027368 |                      | 54 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|  | Antihypertensives    |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14080048             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1027537 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Dizziness; Expired Product Administered; Hyperhidrosis; Injection Site Hypoaesthesia; Palpitations | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14080053             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1027359 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injection   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System

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Site Coldness

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017              | 14080085             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1028768 |                      | 36 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Prn         |                 | Mylan      |                |
|                          | Lisinopril           |                    |                    | C               |                           | 2.5 Mg, Qd           |                 | Mylan      |                |
|                          | Carvedilol           |                    |                    | C               |                           | 6.25 Mg, Bid         |                 | Mylan      |                |
|                          | Digoxin              |                    |                    | C               |                           | 250 Mg, Qd           |                 | Mylan      |                |
|                          | Buspirone            |                    |                    | C               |                           | 15 Mg, Bid           |                 | Mylan      |                |

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017   | 14080146             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1029498 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Heart Rate Increased; Injection Site Haemorrhage | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Mylan      |                |

| <u>FDA Received Date</u>                | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017                             | 14080157                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1030085 |                      | 3 YR            | Male       | USA            |
| <u>Preferred Term</u>                   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017              | 14080158       | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1030326 |                      | 51 YR           | Female     | USA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |



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|  |                          |                      |                    |                 |                           |                      |                 |            |                |
|--|--------------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Drug Dose Omission   |                          | Epipen Auto-Injector |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14080170                 | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1030108 |                      | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Urticaria  | Epipen Auto-Injector     |                      |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14080175                 | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1030899 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event; Off Label Use  | Epipen Auto-Injector     |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14080283                 | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1033455 |                      | 10 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Injection Site Erythema  | Epipen Auto-Injector     |                      |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017  | 14080322                 | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1033634 |                      | 10 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Injury Associated With Device; Needle Issue | Epipen Jr. Auto-Injector |                      |                    | S               | Intramuscular             | 0.15 Mg, Prn         |                 | Mylan      |                |

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| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017                        | 14080335             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1033681 |                      | 19 YR           | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                     | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14080336             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1034913 |                      | 58 YR           | Male       | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14080340             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1034832 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                     | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14080346             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1034887 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                     | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>           | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                        | 14080357             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1034272 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>              | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                     | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017   | 14080380             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1033595 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Anxiety; Expired Product Administered; Palpitations | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14080387             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1034859 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14080436             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1034280 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Delayed   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14080456             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1034875 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14080463             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1037394 |                      | 16 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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|                                |                         |                      |                    |                 |                           |                      |                 |            |                |
|--------------------------------|-------------------------|----------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective               |                         | Epipen Auto-Injector |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                    | 14080511                | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1037463 |                      | 59 YR           | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective               | Epipen Auto-Injector    |                      |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                    | 14080655                | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1039013 |                      | 60 YR           | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                 | Epipen Auto-Injector    |                      |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                    | 14080657                | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1039349 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                 | Epipen Auto-Injector    |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                    | 14080667                | EXPEDITED (15-DAY)   |                    |                 | US-MYLANLABS-2017M1038843 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>          | <u>Product</u>          | <u>Comp.</u>         | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product | Epipen Auto-Injector    |                      |                    | S               |                           | Unk                  |                 | Mylan      |                |
|                                | Synthroid               |                      |                    | C               |                           | Unk                  |                 | Mylan      |                |
|                                | Multivitamin /00097801/ |                      |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>       | <u>Case #</u>           | <u>Case Type</u>     | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017                    | 14080681                | EXPEDITED (15-DAY)   |                    | OT              | US-MYLANLABS-2017M1038578 |                      | 7 YR            | Male       | USA            |

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| <a href="#">Preferred Term</a>             | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Injection Site Laceration;<br>Needle Issue | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017                                | 14081783                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-<br>2017M1046325 |                               | 18 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                             | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017                                | 14081800                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-<br>2017M1044458 |                               | 2 YR                     | Female              | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                             | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017                                | 14081868                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-<br>2017M1042148 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                           | Epipen Auto-Injector     |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|  | Antibiotic /00011701/    |                           |                             | C                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>          | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 12-Oct-2017                                | 14081908                 | EXPEDITED (15-DAY)        |                             |                          | US-MYLANLABS-<br>2017M1041506 |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>             | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose<br>Omission      | Epipen Jr. Auto-Injector |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Oct-2017   | 14081965                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1048947 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; No Adverse Event          | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14082523                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1052585 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Pain; Injury Associated With Device; Needle Issue; Product Quality Issue | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14082689                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1054068 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Coldness; Injection Site Hypoaesthesia   | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Oct-2017   | 14082759                 | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1055550 |                      | 55 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen Auto-Injector     |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
|   | Gabapentin               |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |

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|   |                      |                    |                    |                 |                           |                      |                 |            |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Nexium /01479302/   |                      |                    | C                  |                 | Unk                       |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Oct-2017   | 13541664             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1027755 |                      | 18 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission; Drug Effect Decreased; Expired Product Administered | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |
|   | Melatonin            |                    |                    | C               |                           | Unk, Prn, Bedtime    |                 | Mylan      |                |
|   | Claritin /00917501/  |                    |                    | C               |                           | Unk, Prn             |                 | Mylan      |                |
|   | Symbicort            |                    |                    | C               |                           | 2 Df, Qd             |                 | Mylan      |                |
|   | Ventolin Hfa         |                    |                    | C               |                           | 2 Df, Prn, Q6hrs     |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Oct-2017   | 14081772             | DIRECT             | Y                  |                 |                           |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Dispensing Error   | Epipen               |                    |                    | S               |                           |                      |                 |            |                |
|   | Epipen               |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Oct-2017   | 14097947             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1043809 |                      | 68 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Oct-2017   | 14097954             | EXPEDITED (15-DAY) |                    |                 | US-MYLANLABS-2017M1047248 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

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| Device Failure   | Epipen Auto-Injector | S                  | Unk                | Mylan           |                          |                      |                 |            |                |
|--|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Oct-2017  | 14099352             | NON-EXPEDITED      |                    | LT, OT          | US-PFIZER INC-2017212415 |                      | 18 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Drug Effect Decreased; Expired Product Administered; Product Quality Issue | Epipen               |                    |                    | S               | Intramuscular            | Unk Unk, Once        |                 | Pfizer     |                |
|  | Epipen               |                    |                    | S               | Intramuscular            | 0.3 Mg, Unk          |                 | Pfizer     |                |
|  | Melatonin            |                    |                    | C               |                          | Unk, Prn, Bedtime    |                 |            |                |
|  | Claritin             |                    |                    | C               |                          | Unk, Prn             |                 |            |                |
|  | Symbicort            |                    |                    | C               |                          | 2 Df, Qd             |                 |            |                |
|  | Ventolin Hfa         |                    |                    | C               |                          | 2 Df, Prn, Q6hrs     |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Oct-2017  | 13585823             | EXPEDITED (15-DAY) |                    | OT              | FR-PFIZER INC-2017232840 |                      | 55 YR           | Female     | FRA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Haematoma; Vasoconstriction                         | Epipen               |                    |                    | S               | Intramuscular            | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Oct-2017  | 14057313             | NON-EXPEDITED      |                    | DE, OT          | US-PFIZER INC-K201101077 |                      | 20 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Drug Ineffective; Needle Issue; Product Quality Issue                      | Epipen               |                    |                    | S               | Intramuscular            | 0.3 Mg, Once         |                 | Pfizer     |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 19-Oct-2017   | 13418084             | EXPEDITED (15-DAY) |                    | HO              | JP-PFIZER INC-2017147135  |                      | 73 YR           | Female     | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Issue; Drug Dose Omission; Product Quality Issue | Epipen 0.3mg         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Oct-2017   | 14112027             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017454076  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness; Tremor   | Epipen               |                    |                    | S               |                           | 0.3 Mg, Once         |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Oct-2017   | 14117551             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2017M1061575 |                      | 68 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Oct-2017   | 14121277             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2017M1056913 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered            | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Oct-2017   | 14121470             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2017M1061138 |                      |                 | Male       | USA            |

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product By Child; Anxiety; Expired Product Administered; Flushing | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 | 0.15 Mg, Prn                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2017  | 14121867                 | EXPEDITED (15-DAY)        |                             | DE                       | US-MYLANLABS-2017M1065880     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission   | Epipen Auto-Injector     |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
|  | Epipen Auto-Injector     |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Oct-2017  | 14133564                 | EXPEDITED (15-DAY)        |                             | HO, OT                   | CA-MYLANLABS-2017M1052579     |                               |                          | Male                | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission   | Epipen                   |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
|  | Epipen                   |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Oct-2017  | 13428905                 | EXPEDITED (15-DAY)        |                             | HO                       | JP-MYLANLABS-2017M1021949     |                               | 73 YR                    | Female              | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Issue; Drug Dose Omission; Product Quality Issue                  | Epipen                   |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 30-Oct-2017  | 14142718                 | EXPEDITED (15-DAY)        |                             | DE, HO, LT, OT           | GB-PFIZER INC-2017460071      |                               | 13 YR                    | Male                | GBR                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

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|  |                      |                    |                    |                 |                           |                      |                 |            |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Cardiac Arrest; Expired Product Administered | Epipen               |                    | S                  |                 |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Oct-2017                                  | 14145648             | EXPEDITED (15-DAY) |                    | DE, HO, LT, OT  | GB-MYLANLABS-2017M1067243 |                      | 13 YR           | Male       | GBR            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Expired Product Administered | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Nov-2017                                  | 14134880             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1067121 |                      | 13 YR           | Male       | USA            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission           | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Nov-2017                                  | 14162143             | EXPEDITED (15-DAY) |                    | OT              | PHHY2017GB162350          |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>                        | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Systemic Mastocytosis                        | Omeprazole           |                    |                    | S               | Unknown                   | 40 Mg, Qd            |                 | Novartis   |                |
|  | Ranitidine           |                    |                    | S               | Unknown                   | 150 Mg, Bid          |                 |            |                |
|  | Sodium Clodronate    |                    |                    | S               | Unknown                   | 1040 Mg, Qd          |                 |            |                |
|  | Prednisolone         |                    |                    | S               | Unknown                   | 10 Mg, Qd            |                 |            |                |
|  | Sodium Cromoglycate  |                    |                    | S               | Oral                      |                      |                 |            |                |
|  | Cyclizine            |                    |                    | S               | Unknown                   | 50 Mg, Tid           |                 |            |                |
|  | Epipen               |                    |                    | S               | Unknown                   | Unk Unk, Prn         |                 |            |                |
| <u>FDA Received Date</u>                     | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Nov-2017                                  | 14163260             | NON-EXPEDITED      |                    | DE, OT          | US-PFIZER INC-K200900284  |                      |                 | Female     | USA            |

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## Freedom of Information Act (FOIA)

### Detailed Report

| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Device Use Issue; Drug Dose Omission; Drug Ineffective; Malaise; Needle Issue; Product Quality Issue | Epipen                                    |                    |                    | S               |                           | 0.3 Mg, Single       |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Nov-2017  | 14175785                                  | EXPEDITED (15-DAY) |                    | DE              | US-PFIZER INC-K200800145  |                      | 65 YR           | Male       | ITA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Underdose  | Epipen Jr                                 |                    |                    | S               | Intramuscular             | 165 Ug, Single       |                 | Pfizer     |                |
|  | Epipen Jr                                 |                    |                    | S               |                           |                      |                 | Pfizer     |                |
|  | Epipen Jr                                 |                    |                    | S               |                           |                      |                 | Pfizer     |                |
|  | Epipen Jr                                 |                    |                    | S               |                           |                      |                 | Pfizer     |                |
|  | Bentelan                                  |                    |                    | S               |                           |                      |                 | Pfizer     |                |
|  | Bentelan                                  |                    |                    | S               |                           | Unk                  |                 |            |                |
|  | Bentelan                                  |                    |                    | S               |                           |                      |                 |            |                |
|  | Trimeton                                  |                    |                    | S               |                           |                      |                 |            |                |
|  | Trimeton                                  |                    |                    | S               |                           |                      |                 |            |                |
| Trimeton   |   |                    | S                  |                 |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Nov-2017  | 14177871                                  | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1051669 |                      | 73 YR           | Male       | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Olmotec                                   |                    |                    | C               |                           | 1 Df, 1x/Day         |                 | Mylan      |                |
|  | Feburic                                   |                    |                    | C               |                           | 1 Df, 1x/Day         |                 | Mylan      |                |
|  | Grimac                                    |                    |                    | C               |                           | 1 Df, 3x/Day         |                 | Mylan      |                |
|  | Polysilo                                  |                    |                    | C               |                           | 1 Df, 3x/Day         |                 | Mylan      |                |
|  | Camostat                                  |                    |                    | C               |                           | 1 Df, 3x/Day         |                 | Mylan      |                |

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| Loxoprofen   |   |                    | C                  |                 | 1 Df, 1x/Day              |                      |                 | Mylan      |                |
|--|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Nov-2017  | 14180005                                  | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017477196  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Blood Pressure Increased; Device Failure; Device Use Issue; Heart Rate Increased; Needle Issue | Epipen                                    |                    |                    | S               | Transdermal               | 0.3 Mg, Prn          |                 | Pfizer     |                |
|  | Epipen                                    |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Nov-2017  | 13894397                                  | EXPEDITED (15-DAY) |                    | HO              | JP-MYLANLABS-2017M1051666 |                      | 58 YR           | Male       | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Expired Device Used; Product Quality Issue                   | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Nov-2017  | 14099234                                  | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2017M1063403 |                      | 7 YR            | Male       | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Malfunction   | Epipen Jr Adrenaline Auto-Injector        |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Nov-2017  | 14183677                                  | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017487871  |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Arthralgia; Expired  | Epipen                                    |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |

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Product Administered

| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------------------|----------------------|-----------------|------------|----------------|
| 14-Nov-2017   | 14188017             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1070811             |                      | 12 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular                         | 0.3 Mg, Once         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 14-Nov-2017   | 14188034             | EXPEDITED (15-DAY) |                    | DE, OT          | IT-MYLANLABS-PF-K200800145            |                      | 65 YR           | Male       | ITA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction; Drug Ineffective; Product Quality Issue; Underdose                    | Epipen               |                    |                    | S               | Intramuscular                         | 165 Mcg, Total       |                 | Mylan      |                |
|   | Epipen               |                    |                    | S               |                                       |                      |                 | Mylan      |                |
|   | Bentelan             |                    |                    | S               | Unknown                               | Unk                  |                 | Mylan      |                |
|   | Trimeton /00072502/  |                    |                    | S               | Unknown                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Nov-2017   | 14195277             | EXPEDITED (15-DAY) |                    | DE, OT          | DK-PFIZER INC-K200701131              |                      | 70 YR           | Male       | GBR            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cardiac Arrest; Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen               |                    |                    | S               | Subcutaneous                          | 0.3 Mg, As Needed    |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               | Subcutaneous                          | 0.3 Mg, As Needed    |                 | Pfizer     |                |
|   | Adrenalin /00003901/ |                    |                    | S               | Intravenous (not otherwise specified) | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                  | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Nov-2017   | 14196668             | EXPEDITED (15-DAY) |                    | HO              | ZA-MYLANLABS-2017M1071794             |                      |                 | Male       | ZAF            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                          | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Underdose   | Epipen               |                    |                    | S               |                                       | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--|----------------------|-----------------|---------------------------------|----------------|
| 17-Nov-2017   | 14029939       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1061689                          |                      | 60 YR           | Male                            | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen         |                    |                    | S               |  | Unk                  |                 | Mylan                           |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 17-Nov-2017   | 14201735       | NON-EXPEDITED      |                    | OT              | US-PFIZER INC-2017490659                           |                      |                 | Female                          | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue | Epipen         |                    |                    | S               |  | Unk                  |                 | Pfizer                          |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>                               | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>                      | <u>Country</u> |
| 18-Nov-2017   | 14202598       | EXPEDITED (15-DAY) |                    | DE, LT, OT      | GB-INTERNATIONAL MEDICATION SYSTEMS, LIMITED-20345 |                      | 70 YR           | Male                            | GBR            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                                       | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>                      |                |
| Cardiac Arrest; Death; Drug Ineffective; Pulse Absent                     | Adrenalin      |                    |                    | S               | Intravenous (not otherwise specified)              |                      |                 | International Medication System |                |
|   | Adrenalin      |                    |                    | S               |  |                      |                 |                                 |                |
|   | Epipen         |                    |                    | S               | Intramuscular                                      |                      |                 |                                 |                |
|   | Epipen         |                    |                    | S               | Intramuscular                                      |                      |                 |                                 |                |
|   | Epipen         |                    |                    | S               | Intramuscular                                      |                      |                 |                                 |                |
|   | Epipen         |                    |                    | S               | Intramuscular                                      |                      |                 |                                 |                |
|   | Epipen         |                    |                    | S               | Intramuscular                                      |                      |                 |                                 |                |

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| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 20-Nov-2017  | 14205748                | EXPEDITED (15-DAY)        |                             | OT                       | GB-PFIZER INC-2017121537      |                               | 3 YR                     | Male                | GBR                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Laceration; Pain; Scar; Wrong Technique In Product Usage Process | Epipen<br>Epipen        |                           |                             | S<br>S                   |                               | Unk                           |                          | Pfizer<br>Pfizer    |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Nov-2017  | 14208637                | EXPEDITED (15-DAY)        |                             | LT, OT                   | CA-MYLANLABS-2017M1061147     |                               |                          | Female              | CAN                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission                               | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 21-Nov-2017  | 14209628                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017499106      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Expired Product Administered     | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Nov-2017  | 14177886                | EXPEDITED (15-DAY)        |                             | DE, HO, OT               | CH-MYLANLABS-2017M1071669     |                               |                          | Male                | CHE                     |
| <a href="#">Preferred Term</a>                                   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Respiratory Distress   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Nov-2017  | 14213203                | EXPEDITED (15-DAY)        |                             | OT                       | CA-MYLANLABS-2017M1072189     |                               | 4 YR                     | Female              | CAN                     |



# FDA Adverse Event Reporting System

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| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Device Failure   | Epipen Jr               |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Nov-2017  | 14213314                | EXPEDITED (15-DAY)        |                             | LT, OT                   | CA-MYLANLABS-2017M1066958     |                               |                          | Female              | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Nov-2017  | 14213381                | EXPEDITED (15-DAY)        |                             | LT                       | US-MYLANLABS-2017M1072839     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity;<br>Respiratory Arrest  | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk, Prn                      |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Nov-2017  | 14214119                | EXPEDITED (15-DAY)        |                             | OT                       | CA-PFIZER INC-2017483756      |                               |                          | Male                | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device<br>Use Issue; Drug Dose<br>Omission; Product Quality<br>Issue | Epipen                  |                           |                             | S                        |                               |                               |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Nov-2017  | 14015823                | EXPEDITED (15-DAY)        |                             | OT                       | JP-MYLANLABS-2017M1060834     |                               | 71 YR                    | Male                | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device<br>Use Issue; No Adverse<br>Event; Product Quality<br>Issue   | Epipen                  |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
|  | Pitavastatin            |                           |                             | C                        | Oral                          | 2 Mg, Qd                      |                          | Mylan               |                         |

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|   |  |                    |                    |                  |                           |                      |                 |            |                |  |
|---|--|--------------------|--------------------|------------------|---------------------------|----------------------|-----------------|------------|----------------|--|
| Amlodipine  |  |                    | C                  |                  | Oral                      |                      | 5 Mg, Qd        |            | Mylan          |  |
| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 26-Nov-2017   | 14225783                                   | DIRECT             |                    | LT               |                           |                      | 42 YR           | Female     | USA            |  |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure; Device Malfunction  | Epipen Allergy Meds Birth Control Vitamins |                    |                    | S<br>C<br>C<br>C |                           |                      |                 | Mylan      |                |  |
| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 28-Nov-2017   | 14191245                                   | EXPEDITED (15-DAY) |                    | DE, HO, OT       | CH-PFIZER INC-2017486549  |                      |                 | Male       | CHE            |  |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Respiratory Distress  | Epipen                                     |                    |                    | S                |                           | Unk                  |                 | Pfizer     |                |  |
| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 28-Nov-2017   | 14232052                                   | EXPEDITED (15-DAY) |                    | OT               | CA-MYLANLABS-2017M1071158 |                      |                 | Male       | CAN            |  |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure; Drug Dose Omission  | Epipen                                     |                    |                    | S                |                           | Unk                  |                 | Mylan      |                |  |
| <u>FDA Received Date</u>  | <u>Case #</u>                              | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>  | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |  |
| 30-Nov-2017   | 12729044                                   | EXPEDITED (15-DAY) |                    | DE               | US-MYLANLABS-2016M1037118 |                      | 17 YR           | Male       | USA            |  |
| <u>Preferred Term</u>   | <u>Product</u>                             | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>      | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |  |
| Device Failure; Device Use Issue; Drug Dose Omission; Product Quality Issue | Epipen Auto-Injector                       |                    |                    | S                | Intramuscular             | Unk, Prn             |                 | Mylan      |                |  |

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| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 04-Dec-2017              | 14080530      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2017M1037863 |                      |            | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u>           | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|--------------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; No Adverse Event | Epipen Jr. Auto-Injector |              |            | S           |              | Unk                |                 | Mylan      |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|----------------------|----------------------|------------|------------|----------------|
| 05-Dec-2017              | 13243324      | EXPEDITED (15-DAY) |                    | HO              | ALCN2017CA001343     |                      | 52 YR      | Male       | CAN            |

| <u>Preferred Term</u> | <u>Product</u>            | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u>  | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|---------------------------|--------------|------------|-------------|---------------|--------------------|-----------------|------------|
| Hypersensitivity      | Vigamox                   |              |            | S           | Ophthalmic    | Unk Unk, Tid       |                 |            |
|                       | Betoptic                  |              |            | S           | Ophthalmic    | Unk Unk, Qd        |                 |            |
|                       | Olopatadine               |              |            | S           | Ophthalmic    |                    |                 |            |
|                       | Amlodipine                |              |            | S           | Oral          | 10 Mg, Qd          |                 |            |
|                       | Besivance                 |              |            | S           | Ophthalmic    | Unk Unk, Tid       |                 |            |
|                       | Cialis                    |              |            | S           | Unknown       |                    |                 |            |
|                       | Epipen Jr                 |              |            | S           | Intramuscular | Unk                |                 |            |
|                       | Nasonex                   |              |            | S           |               | 2 Df, Qd           |                 |            |
|                       | Prednisolone "Ratiopharm" |              |            | S           | Unknown       | Unk Unk, Qid       |                 |            |
|                       | Prednisolone "Ratiopharm" |              |            | S           | Unknown       | Unk Unk, Tid       |                 |            |
|                       | Prednisolone "Ratiopharm" |              |            | S           | Unknown       | Unk Unk, Bid       |                 |            |
|                       | Prednisone                |              |            | S           | Unknown       | 50 Mg, Tid         |                 |            |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|--------------------------|----------------------|------------|------------|----------------|
| 05-Dec-2017              | 14252617      | EXPEDITED (15-DAY) |                    | DE              | JP-PFIZER INC-2017518542 |                      | 68 YR      | Male       | JPN            |

| <u>Preferred Term</u> | <u>Product</u> | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|-----------------------|----------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Death                 | Epipen 0.3mg   |              |            | S           |              |                    |                 | Pfizer     |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 07-Dec-2017                                    | 14260184       | EXPEDITED (15-DAY) |                    | DE, OT          | JP-PFIZER INC-2017520304  |                      | 80 YR           | Male       | JPN            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death  | Epipen 0.3mg   |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Dec-2017                                    | 14260247       | EXPEDITED (15-DAY) |                    | DE, OT          | JP-PFIZER INC-2017520310  |                      | 64 YR           | Female     | JPN            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death  | Epipen 0.3mg   |                    |                    | S               |                           |                      |                 | Pfizer     |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-Dec-2017                                    | 14260386       | EXPEDITED (15-DAY) |                    | OT              | CH-MYLANLABS-2017M1076268 |                      |                 | Female     | CHE            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction; Underdose                  | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Dec-2017                                    | 14033609       | EXPEDITED (15-DAY) |                    | HO              | AU-MYLANLABS-2017M1061994 |                      |                 | Female     | AUS            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective; Underdose    | Epipen         |                    |                    | S               |                           | 300mcg/2ml, Unk      |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Dec-2017                                    | 14264330       | NON-EXPEDITED      |                    |                 | US-JAZZ-2014-US-008487    |                      | 53 YR           | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Diplopia; Disorientation; Drug Resistance; Eye | Xyrem          |                    |                    | S               | Oral                      | 3g, Bid              |                 | Jazz       |                |

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|                              |                     |   |              |             |      |
|------------------------------|---------------------|---|--------------|-------------|------|
| Pain; Fatigue; Milk Allergy; | Xyrem               | S | Oral         | 3.75g, Bid  | Jazz |
| Muscle Spasms; Poverty       | Xyrem               | S |              |             | Jazz |
| Of Speech; Rash; Vision      | Epipen              | S |              |             |      |
| Blurred                      | Xolair              | C | Subcutaneous | Unk         |      |
|                              | Potassium           | C | Oral         | 10 Meq, Qd  |      |
|                              | Estradiol           | C | Oral         | 2 Mg, Qd    |      |
|                              | Hydrochlorothiazide | C | Oral         | 12.5 Mg, Qd |      |

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Dec-2017   | 14274815                 | EXPEDITED (15-DAY) |                    | HO              | US-MYLANLABS-2017M1077321 |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cough; Off Label Use; Scratch; Skin Discolouration; Urticaria; Wrong Technique In Product Usage Process | Epipen Jr. Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 12-Dec-2017              | 14276544       | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2017M1030563 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Effect Delayed      | Epipen         |                    |                    | S               | Intramuscular             | 0.3 Mg, Once         |                 | Mylan      |                |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| 12-Dec-2017   | 14280494       | EXPEDITED (15-DAY) |                    | HO              | US-PFIZER INC-2017531946 |                      | 2 YR            | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Cough; Off Label Use; Scratch; Skin Discolouration; Urticaria; Wrong Technique In Product Usage Process | Epipen Jr      |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |

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| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|--------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 13-Dec-2017  | 14226204                 | EXPEDITED (15-DAY)        |                             | LT                       | US-PFIZER INC-2017504891      |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Hypersensitivity;<br>Respiratory Arrest  | Epipen                   |                           |                             | S                        |                               | Unk, As Needed (Prn)          |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 14-Dec-2017  | 14287689                 | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1078734     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Expired Product Administered; No Adverse Event; Wrong Technique In Product Usage Process | Epipen Jr. Auto-Injector |                           |                             | S                        | Intramuscular                 |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2017  | 13378022                 | EXPEDITED (15-DAY)        |                             | DE, OT                   | AU-PFIZER INC-2017126206      |                               |                          | Male                | AUS                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death; Drug Ineffective  | Epipen                   |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2017  | 14289743                 | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017531945      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective   | Epipen                   |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>   | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2017  | 14292836                 | EXPEDITED (15-DAY)        |                             | DE, OT                   | JP-PFIZER INC-2017530695      |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>  | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |   |                           |                             |                          |                               |                               |                          |                     |                         |
|--|---|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Death; Drug Administration Error   |   | Epipen                    |                             | S                        |                               | 1 Df, Single                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2017  | 14292870  | EXPEDITED (15-DAY)        |                             | DE, OT                   | JP-MYLANLABS-2017M1077839     |                               | 64 YR                    | Female              | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death  | Epipen  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2017  | 14292878  | EXPEDITED (15-DAY)        |                             | DE, OT                   | JP-MYLANLABS-2017M1077838     |                               | 80 YR                    | Male                | JPN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death  | Epipen  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 15-Dec-2017  | 14293152  | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2017537955      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product; Injury Associated With Device; Product Quality Issue; Sensory Loss | Epipen  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 17-Dec-2017  | 13982270  | EXPEDITED (15-DAY)        |                             | OT                       | NL-MYLANLABS-2017M1058692     |                               | 14 YR                    | Female              | NLD                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective; No Adverse Event   | Epipen300 Microgram, Oplossing Voor Injectie In Voorgevulde Pen |                           |                             | S                        |                               | 1 Mg/MI, Unk                  |                          | Mylan               |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|-----------------------------------|---|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 18-Dec-2017                       | 13670527                                  | EXPEDITED (15-DAY)        |                             | OT                       | FI-MYLANLABS-2017M1036217     |                               |                          | Female              | FIN                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure                    | Epipen (Epinephrine) Auto Injector 0.3 Mg |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 18-Dec-2017                       | 14298415                                  | EXPEDITED (15-DAY)        |                             | HO                       | AU-MYLANLABS-2017M1077365     |                               |                          | Female              | AUS                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthma                            | Epipen                                    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Dec-2017                       | 14307361                                  | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017536095      |                               | 18 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Dihydrotestosterone Increased     | Epipen 0.3mg                              |                           |                             | S                        | Intramuscular                 | 1 Df, Single                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Dec-2017                       | 14307531                                  | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017537840      |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Injury Associated With Device     | Epipen Jr                                 |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a> | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Dec-2017                       | 14310160                                  | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2017537839      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>    | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                     |   |               |                    |        |
|--|---------------------|---|---------------|--------------------|--------|
| Ear Swelling; Pruritus<br>Generalised; Urticaria | Epipen              | S | Intramuscular | 0.3 Mg, Unk        | Pfizer |
|  | Dayquil             | S | Oral          | 30 ML, Qd (1 Dose) |        |
|  | Benadryl /00000402/ | S |               | Unk                |        |

| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>         | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|------------------------------|----------------------|-----------------|------------|----------------|
| 21-Dec-2017   | 14310032       | EXPEDITED (15-DAY) |                    | OT              | AU-PFIZER INC-<br>2017538437 |                      |                 | Female     | AUS            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                 | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product; Injury Associated<br>With Device | Epipen         |                    |                    | S               |                              | Unk                  |                 | Pfizer     |                |

| <u>FDA Received Date</u>                           | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| 21-Dec-2017  | 14313880       | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-<br>2017M1077414 |                      |                 | Female     | AUS            |
| <u>Preferred Term</u>                              | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injury Associated With<br>Device; No Adverse Event | Epipen         |                    |                    | S               |                               |                      |                 | Mylan      |                |

| <u>FDA Received Date</u>      | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u> | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------|----------------|--------------------|--------------------|-----------------|----------------------|----------------------|-----------------|------------|----------------|
| 22-Dec-2017                   | 9558287        | EXPEDITED (15-DAY) |                    | HO, OT          | CA-ROCHE-1278850     |                      | 47 YR           | Female     | CAN            |
| <u>Preferred Term</u>         | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>         | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Pain Upper;         | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Anaphylactic Shock;           | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Aphonia; Asthma; Breast       | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Pain; Bronchitis; Cellulitis; | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Cellulitis Streptococcal;     | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Contusion; Cough;             | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Decreased Appetite;           | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Dizziness; Drug               | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Ineffective; Ecchymosis;      | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Eczema; Fatigue; Food         | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Allergy; Food Intolerance;    | Xolair         |                    |                    | S               | Subcutaneous         |                      |                 |            |                |
| Generalised Erythema;         |                |                    |                    |                 |                      |                      |                 |            |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|                           |                   |   |              |                   |
|---------------------------|-------------------|---|--------------|-------------------|
| Head Injury; Headache;    | Xolair            | S | Subcutaneous |                   |
| Heart Rate Decreased;     | Xolair            | S | Subcutaneous | 1 Ot              |
| Hypersensitivity;         | Xolair            | S | Subcutaneous |                   |
| Inappropriate Schedule Of | Xolair            | S | Subcutaneous |                   |
| Drug Administration;      | Xolair            | S | Subcutaneous |                   |
| Incision Site Pain;       | Xolair            | S | Subcutaneous |                   |
| Injection Site Reaction;  | Xolair            | S | Subcutaneous |                   |
| Insomnia; Mastitis;       | Xolair            | S | Subcutaneous |                   |
| Nasopharyngitis; Nausea;  | Xolair            | S | Subcutaneous |                   |
| Off Label Use;            | Xolair            | S | Subcutaneous |                   |
| Osteoarthritis; Pain In   | Xolair            | S | Subcutaneous |                   |
| Extremity; Poor Quality   | Xolair            | S | Subcutaneous |                   |
| Sleep; Pruritus           | Xolair            | S | Subcutaneous |                   |
| Generalised; Pulmonary    | Xolair            | S | Subcutaneous |                   |
| Congestion; Rash          | Xolair            | S | Subcutaneous |                   |
| Erythematous; Secretion   | Xolair            | S | Subcutaneous |                   |
| Discharge; Self Esteem    | Xolair            | S | Subcutaneous |                   |
| Decreased; Sensation Of   | Xolair            | S | Subcutaneous |                   |
| Foreign Body; Skin        | Xolair            | S | Subcutaneous |                   |
| Infection; Sneezing;      | Xolair            | S | Subcutaneous |                   |
| Vitamin D Deficiency;     | Xolair            | S | Subcutaneous |                   |
| Vomiting                  | Xolair            | S | Subcutaneous |                   |
|                           | Benadryl (Canada) | S | Unknown      | 2 Df (50 Mg), Unk |
|                           | Benadryl (Canada) | S | Unknown      |                   |
|                           | Benadryl (Canada) | S | Unknown      |                   |
|                           | Benadryl (Canada) | S | Unknown      |                   |
|                           | Reactine (Canada) | S | Unknown      | Qhs (At Bed Time) |
|                           | Reactine (Canada) | S | Unknown      | Qhs (At Bedtime)  |
|                           | Reactine (Canada) | S | Unknown      | Unk               |
|                           | Epipen            | S | Unknown      |                   |
|                           | Clavulin          | S | Unknown      | Unk               |
|                           | Flovent           | C | Unknown      |                   |
|                           | Avamys            | C | Unknown      |                   |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 22-Dec-2017   | 14316678                | NON-EXPEDITED             |                             | OT                       | US-PFIZER INC-2017537836      |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Ineffective                                    | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Dec-2017   | 14324630                | EXPEDITED (15-DAY)        |                             | OT                       | AU-MYLANLABS-2017M1078936     |                               |                          | Male                | AUS                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Needle Issue; Product Quality Issue | Epipen                  |                           |                             | S                        |                               | 300mcg/2ml, Unk               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 26-Dec-2017   | 14325204                | EXPEDITED (15-DAY)        |                             | DE, OT                   | JP-MYLANLABS-2017M1079617     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death; Drug Administration Error                    | Epipen                  |                           |                             | S                        |                               | 1 Df, Single                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Dec-2017   | 14287273                | EXPEDITED (15-DAY)        |                             | HO, OT                   | AU-PFIZER INC-2017531951      |                               |                          | Female              | AUS                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Asthma; Reaction To Preservatives                   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>                   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 27-Dec-2017   | 14330036                | NON-EXPEDITED             |                             |                          | US-PFIZER INC-2017548432      |                               | 3 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>                      | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|   |                     |                    |                    |                 |                               |                      |                 |            |                |
|---|---------------------|--------------------|--------------------|-----------------|-------------------------------|----------------------|-----------------|------------|----------------|
| Administration Site<br>Laceration; Administration<br>Site Scar  |                     | Epipen             | S                  | Unknown         | Unk                           | Unknown              |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Dec-2017   | 14279282            | EXPEDITED (15-DAY) |                    | DE              | JP-MYLANLABS-<br>2017M1077093 |                      | 68 YR           | Male       | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death   | Epipen              |                    |                    | S               |                               | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Dec-2017   | 14332117            | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2017546072  |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device<br>Use Issue; Drug Dose<br>Omission; Dyspnoea;<br>Feeling Abnormal;<br>Paraesthesia Oral;<br>Pharyngeal Oedema;<br>Product Quality Issue | Epipen              |                    |                    | S               | Intramuscular                 | Unk                  |                 | Pfizer     |                |
|   | Benadryl /00000402/ |                    |                    | C               |                               | 20 Mg, Unk           |                 |            |                |
|   | Epi /00166003/      |                    |                    | C               |                               | Unk                  |                 |            |                |
|   | Dexamethasone       |                    |                    | C               |                               | Unk                  |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 28-Dec-2017   | 14333733            | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-<br>2017548462  |                      | 11 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To<br>Product By Child;<br>Erythema; Heart Rate<br>Increased; Hyperhidrosis   | Epipen              |                    |                    | S               | Unknown                       | Unk                  |                 | Pfizer     |                |
|   | Epipen              |                    |                    | S               | Intramuscular                 | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>       | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Dec-2017   | 14338038            | EXPEDITED (15-DAY) |                    | OT              | JP-PFIZER INC-<br>2017545299  |                      |                 | Male       | JPN            |
| <u>Preferred Term</u>   | <u>Product</u>      | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |   |                           |                             |                          |                               |                               |                          |                     |                         |
|--|---|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Accidental Exposure To Product; Injection Site Injury  |   | Epipen 0.15mg             |                             | S                        |                               | Pfizer                        |                          |                     |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Jan-2018  | 14240748                                  | EXPEDITED (15-DAY)        |                             | HO, LT, OT               | GB-MYLANLABS-2017M1074738     |                               | 73 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Issue; Drug Dose Omission; Injury Associated With Device  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 02-Jan-2018  | 14342368                                  | EXPEDITED (15-DAY)        |                             | HO, LT, OT               | GB-PFIZER INC-2017509800      |                               | 73 YR                    | Female              | GBR                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Issue; Drug Dose Omission; Injury Associated With Device; Product Quality Issue | Epipen 0.3mg                              |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Once                  |                          | Pfizer              |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 03-Jan-2018  | 14348110                                  | EXPEDITED (15-DAY)        |                             | OT                       | US-PFIZER INC-2017556058      |                               | 7 YR                     | Male                | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Accidental Exposure To Product By Child; Peripheral Swelling   | Epipen                                    |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Unknown             |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                    | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 04-Jan-2018  | 14246279                                  | EXPEDITED (15-DAY)        |                             | HO, OT                   | CA-MYLANLABS-2017M1074439     |                               | 73 YR                    | Male                | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                   | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

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|                        |        |   |                      |       |
|------------------------|--------|---|----------------------|-------|
| Device Failure; Device | Epipen | S | Six Times Since 2007 | Mylan |
| Use Issue; Drug Dose   | Epipen | S | Unk                  | Mylan |
| Omission; Fall; Head   |        |   |                      |       |
| Injury; Loss Of        |        |   |                      |       |
| Consciousness; Product |        |   |                      |       |
| Quality Issue          |        |   |                      |       |

| <u>FDA Received Date</u> | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 04-Jan-2018              | 14353073             | EXPEDITED (15-DAY) |                    | LT              | US-MYLANLABS-2017M1082670 |                      | 17 YR           | Male       | USA            |
| <u>Preferred Term</u>    | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug     | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| Ineffective; No Adverse  | Epipen Auto-Injector |                    |                    | S               |                           | 0.3 Mg, Unk          |                 | Mylan      |                |
| Event                    | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|-------------------------|-----------------|------------|----------------|
| 05-Jan-2018              | 12934189       | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2016M1048886 |                         |                 | Female     | SWE            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>      | <u>Duration</u> | <u>Mfr</u> |                |
| Wrong Technique In       | Epipen         |                    |                    | S               |                           | Unk                     |                 | Mylan      |                |
| Product Usage Process    | Zyrlex         |                    |                    | C               | Oral                      | Daily Dose: 2 Df Dosage |                 | Mylan      |                |
|                          | Tavegyl        |                    |                    | C               |                           | Form Every Days         |                 | Mylan      |                |
|                          | Tavegyl        |                    |                    | C               |                           | 2 Df, Unk               |                 | Mylan      |                |
|                          | Plavix         |                    |                    | C               |                           | Unk                     |                 | Mylan      |                |
|                          | Plavix         |                    |                    | C               |                           |                         |                 | Mylan      |                |
|                          | Renitec        |                    |                    | C               |                           | Unk                     |                 | Mylan      |                |
|                          | Plendil        |                    |                    | C               | Oral                      | Unk                     |                 | Mylan      |                |
|                          | Betapred       |                    |                    | C               |                           | Unk Unk, Prn            |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 05-Jan-2018              | 14147513      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2017M1067516 |                      | 13 YR      | Female     | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|--------------------------|----------------------|-----------------|------------|----------------|
| Accidental Exposure To Product; Injection Site Pain; Injection Site Swelling; Product Packaging Issue   | Epipen Auto-Injector |                    |                    | S               |                          | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 08-Jan-2018   | 12878279             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2016493949 |                      | 12 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Abdominal Discomfort; Asthenia; Dyspepsia; Nausea   | Epipen               |                    |                    | S               | Intramuscular            | 0.3 Mg, Prn          |                 | Pfizer     |                |
|   | Solu-Medrol          |                    |                    | S               |                          | Unk                  |                 | Pfizer     |                |
|   | Benadryl             |                    |                    | S               |                          | Unk                  |                 |            |                |
|   | Pepcid               |                    |                    | S               |                          | Unk                  |                 |            |                |
|   | Singulair            |                    |                    | C               | Oral                     | 10 Mg, Qam           |                 |            |                |
|   | Clarinetx            |                    |                    | C               | Oral                     | 5 Mg, Qpm            |                 |            |                |
|   | Advair               |                    |                    | C               | Respiratory (inhalation) | 500 Mg, Bid          |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>     | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Jan-2018   | 14251151             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-PFIZER INC-2015373253 |                      | 16 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>             | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Clostridial Infection; Gas Gangrene; Infective Myositis; Injection Site Pain; Necrotising Fasciitis; Necrotising Myositis; Oedema Peripheral; Product Contamination Microbial; Septic Shock; Walking Disability | Epipen               |                    |                    | S               | Intramuscular            | 0.3 Mg, Single       |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               |                          | 0.3 Mg, Unk          |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               |                          |                      |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               |                          |                      |                 | Pfizer     |                |
|   |                      |                    |                    |                 |                          |                      |                 |            |                |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 09-Jan-2018   | 14348185             | EXPEDITED (15-DAY) |                    | OT              | US-PFIZER INC-2017549550  |                      | 13 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Expired Product Administered; Heart Rate Decreased; Incorrect Dose Administered; Needle Issue   | Epinephrine          |                    |                    | S               | Intramuscular             | 1 Df, Unk            |                 | Pfizer     |                |
|   | Epipen               |                    |                    | S               | Intramuscular             | 1 Df, Unk            |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Jan-2018   | 11692755             | EXPEDITED (15-DAY) |                    | HO, LT, OT      | US-MYLANLABS-2015M1038230 |                      | 16 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Clostridial Infection; Gas Gangrene; Infective Myositis; Injection Site Pain; Necrotising Fasciitis; Necrotising Myositis; Oedema Peripheral; Product Contamination Microbial; Septic Shock; Walking Disability | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk Unk, Once        |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk          |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-Jan-2018   | 14306009             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017534677  |                      | 11 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product By Child; Erythema; Foreign Body; Heart Rate Increased; Hyperhidrosis  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 10-Jan-2018   | 14370488             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2018006897  |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Pruritus  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Jan-2018   | 14334663             | EXPEDITED (15-DAY) |                    | OT              | GB-MYLANLABS-2017M1079556 |                      | 27 YR           | Female     | GBR            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Nervousness; Pain In Extremity  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 11-Jan-2018   | 14375660             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2017M1083928 |                      | 23 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; No Adverse Event  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 3 Mg, Unk            |                 | Mylan      |                |
|   | Metoprolol           |                    |                    | C               |                           | 100 Mg, Unk          |                 | Mylan      |                |
|   | Albuterol /00139501/ |                    |                    | C               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Jan-2018   | 14159539             | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2017471176  |                      | 13 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Pain; Injection Site Swelling; Product Packaging Issue | Epipen               |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|------------------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 15-Jan-2018  | 11267404               | EXPEDITED (15-DAY) |                    | DE, HO          | US-MYLANLABS-2015M1022308 |   | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction;<br>Anaphylactic Shock;<br>Blindness; Cardiac Arrest;<br>Condition Aggravated;<br>Injection Site Pruritus;<br>Loss Of Consciousness;<br>Pruritus; Rash<br>Generalised; Sinusitis;<br>Unresponsive To Stimuli | Epipen Auto-Injector   |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk                                   |                 | Mylan      |                |
|  | Ceftriaxone Sandoz     |                    |                    | S               | Intramuscular             | 1 G, Once, Left Buttock                       |                 | Mylan      |                |
|  | Depo-Medrol            |                    |                    | S               | Intramuscular             | 100 Mg, Once, Right Buttock                   |                 | Mylan      |                |
|  | Lidocaine              |                    |                    | S               | Intramuscular             | Unk, Dilute With Ceftriaxone, In Left Buttock |                 | Mylan      |                |
|  | Lidocaine              |                    |                    | S               |                           |   |                 | Mylan      |                |
|  | Cyanocobalamin         |                    |                    | S               | Intramuscular             | 1000 Mg, Once For A While Into Left Shoulder  |                 | Mylan      |                |
|  | Cyanocobalamin         |                    |                    | S               | Unknown                   | Unk Mg, Unk                                   |                 | Mylan      |                |
|  | Cyanocobalamin         |                    |                    | S               | Unknown                   | 1000 Mg, Unk                                  |                 | Mylan      |                |
|  | Vitamin B12 /00056201/ |                    |                    | S               | Intramuscular             | Unk   |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Jan-2018  | 14303185               | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2017538436  |   | 5 YR            | Male       | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Complication Of Device Removal; Device Issue; Drug Ineffective; Injection Site Discolouration; Injection Site Injury; Injection Site Pain; Injury Associated With Device; Needle Issue; Product Quality Issue                      | Epipen Jr              |                    |                    | S               |                           | Unk   |                 | Pfizer     |                |
|  | Epipen Jr              |                    |                    | S               |                           |   |                 | Pfizer     |                |
|  | Benadryl               |                    |                    | C               |                           | Unk   |                 |            |                |

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| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-----------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|---------------------------|-----------------|------------|----------------|
| 17-Jan-2018                 | 14403325             | EXPEDITED (15-DAY) |                    | HO              | JP-MYLANLABS-2018M1004627 |                           |                 | Male       | JPN            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Hospitalisation             | Epipen               |                    |                    | S               |                           |                           |                 |            | Mylan          |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Jan-2018                 | 14403666             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1002779 |                           |                 | Female     | USA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure              | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | Unk                       |                 |            | Mylan          |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Jan-2018                 | 14333815             | EXPEDITED (15-DAY) |                    | HO, OT          | CA-PFIZER INC-2017544567  |                           | 15 YR           | Male       | CAN            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Vomiting  | Epipen               |                    |                    | S               |                           | Unk                       |                 |            | Unknown        |
| <u>FDA Received Date</u>    | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>      | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Jan-2018                 | 14371898             | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-PFIZER INC-2899860     |                           | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>       | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>        | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction;      | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk               |                 |            | Pfizer         |
| Anaphylactic Shock;         | Depo Medrol          |                    |                    | S               | Intramuscular             | 100 Mg, Single            |                 |            | Pfizer         |
| Cardiac Arrest; Condition   | Lidocaine Hcl        |                    |                    | S               | Intramuscular             | Unk, Single               |                 |            | Unknown        |
| Aggravated; Injection Site  | Ceftriaxone Sodium   |                    |                    | S               | Intramuscular             | 1 G, Single               |                 |            | Pfizer         |
| Indentation; Injection Site | Vitamin B12          |                    |                    | S               | Intramuscular             | 1000 Ug, Once, For A      |                 |            |                |
| Pruritus; Loss Of           |                      |                    |                    |                 |                           | While ;Into Left Shoulder |                 |            |                |
| Consciousness; Pruritus;    |                      |                    |                    |                 |                           |                           |                 |            |                |
| Rash Generalised;           |                      |                    |                    |                 |                           |                           |                 |            |                |
| Sinusitis; Sudden Visual    |                      |                    |                    |                 |                           |                           |                 |            |                |
| Loss; Unresponsive To       |                      |                    |                    |                 |                           |                           |                 |            |                |
| Stimuli                     |                      |                    |                    |                 |                           |                           |                 |            |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Jan-2018  | 14406593       | EXPEDITED (15-DAY) |                    | HO              | JP-MYLANLABS-2018M1004616 |                      |                 | Female     | JPN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hospitalisation  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Jan-2018  | 14407289       | EXPEDITED (15-DAY) |                    | OT              | CA-PFIZER INC-2018017819  |                      | 51 YR           | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Condition Aggravated; Nausea; Sinus Tachycardia; Throat Tightness; Vomiting  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 19-Jan-2018  | 14417939       | DIRECT             |                    | HO, OT          |                           |                      | 40 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Abscess   | Epipen         |                    |                    | S               |                           |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Jan-2018  | 14419789       | EXPEDITED (15-DAY) |                    | HO, OT          | US-PFIZER INC-2018026144  |                      | 26 YR           | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock; Device Failure; Device Use Issue; Erythema; Expired Product Administered; Feeling Abnormal; Injection Site Haemorrhage; Injury Associated With Device; Needle Issue; Pain In | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
|  | Epipen         |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |

# FDA Adverse Event Reporting System

## Freedom of Information Act (FOIA)

### Detailed Report

Extremity; Skin Injury;  
Swelling Face

| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|--|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|----------------|----------------|
| 22-Jan-2018  | 14420169                                     | EXPEDITED (15-DAY) |                    | HO, OT          | US-MYLANLABS-2018M1004450 |                      | 26 YR           | Male           | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Anaphylactic Shock;<br>Device Failure; Erythema;<br>Expired Product<br>Administered; Feeling<br>Abnormal; Injection Site<br>Haemorrhage; Injury<br>Associated With Device;<br>Pain In Extremity; Skin<br>Injury; Swelling Face | Epipen Auto-Injector<br>Epipen Auto-Injector |                    |                    | S<br>S          |                           |                      |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 24-Jan-2018  | 14413191                                     | EXPEDITED (15-DAY) |                    | DE, HO, OT      | US-PFIZER INC-2018025491  |                      | 18 YR           | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Brain Injury; Cardiac<br>Arrest; Consciousness<br>Fluctuating; Dyspnoea;<br>Expired Product<br>Administered  | Epipen                                       |                    |                    | S               |                           | Unk                  |                 | Pfizer         |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                                | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 25-Jan-2018  | 14441982                                     | EXPEDITED (15-DAY) |                    | LT, OT          | CA-MYLANLABS-2018M1005519 |                      |                 | Female         | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>                               | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Device Failure; Product<br>Quality Issue   | Epipen                                       |                    |                    | S               | Intramuscular             |                      |                 | Mylan          |                |

# FDA Adverse Event Reporting System

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| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|-------------------------------------|----------------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 29-Jan-2018                         | 14452637             | EXPEDITED (15-DAY) |                    | DE, OT          | PHEH2018US002429          |   | 58 YR           | Female     | USA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction;              | Ceftriaxone Sandoz   |                    |                    | S               | Intramuscular             | 1 G, Once/Single, Left Buttock                |                 | Novartis   |                |
| Anaphylactic Shock;                 | Lidocaine            |                    |                    | S               | Intramuscular             | Unk, Dilute With Ceftriaxone, In Left Buttock |                 |            |                |
| Blindness; Cardiac Arrest;          | Lidocaine            |                    |                    | S               |                           |   |                 |            |                |
| Condition Aggravated;               | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Qd                                    |                 |            |                |
| Injection Site Pruritus;            | Depo-Medrol          |                    |                    | S               | Intramuscular             | 100 Mg, Once, Right Buttock                   |                 |            |                |
| Loss Of Consciousness;              | Vitamin B12          |                    |                    | S               | Intramuscular             | 1000 Ug, Once, For A While Into Left Shoulder |                 |            |                |
| Pruritus; Rash                      | Vitamin B12          |                    |                    | S               | Unknown                   | 1000 Ug, Unk                                  |                 |            |                |
| Generalised; Sinusitis;             |                      |                    |                    |                 |                           |   |                 |            |                |
| Unresponsive To Stimuli             |                      |                    |                    |                 |                           |   |                 |            |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 29-Jan-2018                         | 14454667             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1007337 |   |                 | Female     | USA            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; No                | Epipen Auto-Injector |                    |                    | S               | Intramuscular             |   |                 | Mylan      |                |
| Adverse Event                       | Epipen Auto-Injector |                    |                    | S               | Intramuscular             |   |                 | Mylan      |                |
| <u>FDA Received Date</u>            | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                          | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 30-Jan-2018                         | 14432662             | EXPEDITED (15-DAY) |                    | DE, OT          | CA-PFIZER INC-2018029752  |   |                 | Male       | CAN            |
| <u>Preferred Term</u>               | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                            | <u>Duration</u> | <u>Mfr</u> |                |
| Death; Expired Product Administered | Epipen               |                    |                    | S               |                           | Unk   |                 | Pfizer     |                |

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| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 31-Jan-2018   | 13393153             | EXPEDITED (15-DAY) |                    | DE, OT          | AU-PFIZER INC-2017134714  |                      | 79 YR           | Male       | AUS            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction;                                  | Epipen               |                    |                    | S               |                           | 2 Df, Unk            |                 | Pfizer     |                |
| Myocardial Infarction;                                  | Epipen               |                    |                    | S               |                           | 2 Df, Unk            |                 | Pfizer     |                |
| Product Use Issue                                       |                      |                    |                    |                 |                           |                      |                 |            |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Jan-2018   | 14312717             | EXPEDITED (15-DAY) |                    | LT, OT          | US-MYLANLABS-2017M1079524 |                      | 40 YR           | Female     | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Dose Omission                      | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
|   | Benadryl /00000402/  |                    |                    | C               |                           | 20 Mg, Unk           |                 | Mylan      |                |
|   | Epi /00166003/       |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
|   | Dexamethasone        |                    |                    | C               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Jan-2018   | 14469734             | EXPEDITED (15-DAY) |                    | LT, OT          | CA-MYLANLABS-2018M1005516 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; No Adverse Event; Product Quality Issue | Epipen               |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                                | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 31-Jan-2018   | 14472270             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1005512 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure  | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | 1 Df, Unk            |                 | Mylan      |                |
|   | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|-------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 01-Feb-2018  | 14431618          | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2018M1005158 |                      | 12 YR           | Female     | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; No Adverse Event   | Epipen            |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Feb-2018  | 14473755          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2018040499  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Hypoaesthesia | Epipen            |                    |                    | S               |                           |                      |                 | Unknown    |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Feb-2018  | 12860821          | EXPEDITED (15-DAY) |                    | HO, LT, OT      | PHHY2016AU140855          |                      |                 | Female     | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Tryptase Increased  | Loratadine Sandoz |                    |                    | S               | Unknown                   |                      |                 | Novartis   |                |
|  | Ranitidine        |                    |                    | S               | Unknown                   | Unk                  |                 |            |                |
|  | Interferon Alfa   |                    |                    | S               | Unknown                   |                      |                 |            |                |
|  | Epipen            |                    |                    | S               | Unknown                   |                      |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>     | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Feb-2018  | 14478857          | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2018044765  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>    | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Injection Site Haemorrhage                                 | Epipen            |                    |                    | S               | Unknown                   | Unk                  |                 | Pfizer     |                |



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| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 02-Feb-2018   | 14478998       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2018044761  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Contusion; Injury Associated With Device; Pain  | Epipen Jr      |                    |                    | S               |                           | Unk                  |                 | Pfizer     |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Feb-2018   | 14485007       | NON-EXPEDITED      |                    |                 | US-PFIZER INC-2018046971  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Expired Product Administered; Injection Site Hypoaesthesia          | Epipen         |                    |                    | S               | Unknown                   | Unk                  |                 | Unknown    |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Feb-2018   | 14485903       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2018M1003822 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Underdose; Device Failure; Device Use Issue; Needle Issue; Pallor; Product Quality Issue | Epipen         |                    |                    | S               |                           | 0.15 Mg, Qd          |                 | Mylan      |                |
|   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |
|   | Singulair      |                    |                    | C               | Oral                      | 5 Mg, Qd             |                 | Mylan      |                |
|   | Alvesco        |                    |                    | C               | Endotracheal              | 100 Mg, Qd           |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 05-Feb-2018   | 14488159       | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1008953 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| No Adverse Event; Product Use In  | Epipen         |                    |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
|   | Epipen         |                    |                    | S               |                           |                      |                 | Mylan      |                |

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Unapproved Indication

| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 08-Feb-2018  | 14419963                | EXPEDITED (15-DAY)        |                             | HO, OT                   | US-MYLANLABS-2018M1004129     |                               | 29 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure   | Epipen Auto-Injector    |                           |                             | S                        | Subcutaneous                  | 0.3 Mg, Unk                   |                          | Mylan               |                         |
|  | Epipen Auto-Injector    |                           |                             | S                        | Subcutaneous                  | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018  | 14078893                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1025153     |                               | 17 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Drug Dose Omission; Intentional Product Misuse; Product Colour Issue | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018  | 14080220                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1032455     |                               |                          | Unknown             | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission                                   | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|  | Epipen Auto-Injector    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                                    | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018  | 14080675                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1039346     |                               |                          | Female              | USA                     |
| <a href="#">Preferred Term</a>                                       | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission                                   | Epipen Auto-Injector    |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |

# FDA Adverse Event Reporting System

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| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
|--|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| 16-Feb-2018  | 14081695                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1043147     |                               | 70 YR                    | Female              | USA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission                             | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018  | 14082095                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1047614     |                               | 22 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission                             | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
|  | Epipen Auto-Injector    |                           |                             | S                        |                               |                               |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018  | 14121280                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1056176     |                               | 16 YR                    | Male                | USA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission; Injection Site Haemorrhage | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018  | 14213797                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1072834     |                               |                          | Male                | USA                     |
| <a href="#">Preferred Term</a>                                 | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Drug Dose Omission                             | Epipen Auto-Injector    |                           |                             | S                        |                               | 0.3 Mg, Prn                   |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>                              | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018  | 14293062                | NON-EXPEDITED             |                             |                          | US-MYLANLABS-2017M1078733     |                               |                          | Female              | USA                     |

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| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
|---|-------------------------|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|--------------------------|---------------------|-------------------------|
| Drug Ineffective; Needle Issue  | Epipen Auto-Injector    |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 16-Feb-2018   | 14542528                | EXPEDITED (15-DAY)        |                             | OT                       | CA-MYLANLABS-2018M1012085     |                               | 28 YR                    | Male                | CAN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; No Adverse Event; Product Quality Issue   | Epipen                  |                           |                             | S                        |                               | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Feb-2018   | 14553583                | EXPEDITED (15-DAY)        |                             | OT                       | CA-MYLANLABS-2018M1009644     |                               |                          | Female              | CAN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Device Use Issue; Liquid Product Physical Issue; Needle Issue; No Adverse Event | Epipen Jr.              |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 20-Feb-2018   | 14554977                | EXPEDITED (15-DAY)        |                             | LT, OT                   | CA-MYLANLABS-2018M1011607     |                               |                          | Female              | CAN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Device Failure; Product Quality Issue   | Epipen                  |                           |                             | S                        | Intramuscular                 | Unk                           |                          | Mylan               |                         |
| <a href="#">FDA Received Date</a>   | <a href="#">Case #</a>  | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>      | <a href="#">Sex</a> | <a href="#">Country</a> |
| 22-Feb-2018   | 14563897                | EXPEDITED (15-DAY)        |                             | DE                       | JP-MYLANLABS-2018M1011639     |                               |                          | Unknown             | JPN                     |
| <a href="#">Preferred Term</a>  | <a href="#">Product</a> | <a href="#">Comp.</a>     | <a href="#">OTC</a>         | <a href="#">Role</a>     | <a href="#">Route</a>         | <a href="#">Dosage Text</a>   | <a href="#">Duration</a> | <a href="#">Mfr</a> |                         |
| Death   | Epipen                  |                           |                             | S                        | Intramuscular                 |                               |                          | Mylan               |                         |

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| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|-----------------------|-----------------|------------|----------------|
| 23-Feb-2018   | 14567992             | EXPEDITED (15-DAY) |                    | OT              | NO-MYLANLABS-2018M1012863 |                       | 9 YR            | Female     | NOR            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Adverse Reaction; Expired Product Administered; Headache; Increased Upper Airway Secretion; Nausea  | Epipen Jr            |                    |                    | S               |                           | Unk, Total            |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 24-Feb-2018   | 14569819             | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1012077 |                       |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Incorrect Route Of Drug Administration  | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | Unk                   |                 | Mylan      |                |
|   | Epinephrine          |                    |                    | S               | Subcutaneous              | Unk                   |                 |            |                |
|   | Allegra              |                    |                    | C               |                           |                       |                 | Mylan      |                |
|   | Benadryl /00000402/  |                    |                    | C               |                           |                       |                 | Mylan      |                |
|   | Valaciclovir         |                    |                    | C               |                           |                       |                 | Mylan      |                |
|   | Losartan             |                    |                    | C               |                           |                       |                 | Mylan      |                |
|   | Buspirone            |                    |                    | C               |                           |                       |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 26-Feb-2018   | 14137456             | EXPEDITED (15-DAY) |                    | HO, OT          | CA-MYLANLABS-2017M1067503 |                       | 51 YR           | Female     | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Compartment Syndrome; Device Failure; Gait Disturbance; Injection Site Pain; Limb Injury; Muscle Atrophy; Muscular Weakness; Oedema; Pain In Extremity; Scar; Sensory Disturbance; Walking Aid User | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk           |                 | Mylan      |                |
|   | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk           |                 | Mylan      |                |
|   | Epipen               |                    |                    | S               | Intramuscular             | 0.3 Mg, Unk           |                 | Mylan      |                |
|   | Thrive /01033302/    |                    |                    | C               |                           |                       |                 | Mylan      |                |
|   | Nicoderm             |                    |                    | C               |                           | 21mg/24h              |                 | Mylan      |                |
|   | Pms-Valacyclovir     |                    |                    | C               |                           |                       |                 | Mylan      |                |
|   | Ventolin Hfa         |                    |                    | C               |                           | 100 Mg, 2 Inhalations |                 | Mylan      |                |

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|                             |   |                                       |                            |       |
|-----------------------------|---|---------------------------------------|----------------------------|-------|
| Teva                        | C |                                       | Unk                        | Mylan |
| Alendronate/Cholecalciferol |   |                                       |                            |       |
| D-Tabs                      | C |                                       | 1000ui                     | Mylan |
| Alprazolam                  | C |                                       | 0.5 Mg, Unk                | Mylan |
| Dilaudid                    | C | Oral                                  | 2 Mg, Pm                   | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 2 Mg, Pm                   | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 2 Mg, Pm                   | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 2 Mg, Am                   | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 2 Mg, Every 3 Hr As Needed | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 4 Mg, Every 3 Hr As Needed | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 2 Mg, Unk                  | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 2 Mg, Q4h As Needed        | Mylan |
| Dilaudid                    | C | Subcutaneous                          | 2 Mg, Q3n As Needed        | Mylan |
| Dilaudid                    | C | Oral                                  | 4 Mg, Q3h As Needed        | Mylan |
| Dilaudid                    | C | Oral                                  | 1 Mg, Unk                  | Mylan |
| Esomeprazole                | C |                                       | Unk                        | Mylan |
| Diltiazem Hcl Teva          | C |                                       | 180 Mg, Qd                 | Mylan |
| Rosuvastatin                | C |                                       | 10 Mg, Qd                  | Mylan |
| Mometasone                  | C |                                       | 50 Mg, 2 Inhalations       | Mylan |
| Cal-500                     | C |                                       | 500 Mg, Bid                | Mylan |
| Fentanyl Matrix             | C |                                       | 75 Mg, Per Hr              | Mylan |
| Benadryl                    | C | Intravenous (not otherwise specified) | 50 Mg, Unk                 | Mylan |
| Benadryl                    | C |                                       | Unk                        | Mylan |
| Zantic                      | C | Intravenous (not otherwise specified) | 50 Mg, Unk                 | Mylan |
| Solu-Medrol                 | C | Intravenous (not otherwise specified) | 125 Mg, Unk                | Mylan |
| Nacl                        | C |                                       | Unk                        | Mylan |

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| <u>FDA Received Date</u>                                | <u>Case #</u>    | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>           | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
|---|------------------|--------------------|--------------------|-----------------|--------------------------------|----------------------|-----------------|----------------|----------------|
| 26-Feb-2018   | 14573910         | EXPEDITED (15-DAY) |                    | HO, OT          | CA-MYLANLABS-2018M1013405      |                      | 14 YR           | Female         | CAN            |
| <u>Preferred Term</u>                                   | <u>Product</u>   | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                   | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Device Ineffective;<br>Intentional Product Use<br>Issue | Epipen<br>Epipen |                    |                    | S<br>S          | Intramuscular<br>Intramuscular | Unk                  |                 | Mylan<br>Mylan |                |

| <u>FDA Received Date</u>   | <u>Case #</u>   | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u>   | <u>Mfr Control #</u>     | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|---|--------------------|--------------------|---|--------------------------|---|-----------------|------------|----------------|
| 28-Feb-2018  | 14128538  | EXPEDITED (15-DAY) |                    | HO, OT  | CA-PFIZER INC-2017454302 |   | 51 YR           | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>  | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>   | <u>Route</u>             | <u>Dosage Text</u>  | <u>Duration</u> | <u>Mfr</u> |                |
| Compartment Syndrome;<br>Device Failure; Device<br>Use Issue; Gait<br>Disturbance; Injection Site<br>Pain; Muscle Atrophy;<br>Muscular Weakness;<br>Oedema; Product Quality<br>Issue; Scar; Sensory<br>Disturbance | Epipen<br>Thrive /01033302/<br>Nicoderm<br>Pms-Valacyclovir<br>Ventolin Hfa<br>Alendronate Sodium<br>W/Colecalciferol<br>D-Tabs<br>Alprazolam<br>Dilaudid<br>Apo Esomeprazole<br>Diltiazem Hcl Teva<br>Pms Rosuvastatin<br>Apo Mometasone<br>Ran-Fentanyl |                    |                    | S<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C<br>C | Intramuscular            | 0.3 Mg, Unk<br>2 Mg, Unk<br>21 Mg, Unk<br>500 Mg, Unk<br>100 Ug, Unk<br>70 Mg, Unk<br>1000 Iu, Unk<br>0.5 Mg, Unk<br>2 Mg, Unk<br>40 Mg, Unk<br>180 Mg, Unk<br>10 Mg, Unk<br>50 Ug, Unk<br>75 Ug, Unk |                 | Pfizer     |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 28-Feb-2018              | 14293064      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2017M1078732 |                      |            | Female     | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Drug Ineffective  | Epipen Auto-Injector                    |                    |                    | S               | Intramuscular             | 0.3 Unk, Unk         |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 01-Mar-2018   | 14588152                                | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1013655 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Product Supply Issue  | Epipen                                  |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Mar-2018   | 14309156                                | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2017M1077939 |                      | 5 YR            | Male       | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Complication Of Device Removal; Device Issue; Drug Ineffective; Injection Site Discolouration; Injection Site Injury; Injection Site Pain; Injury Associated With Device; Needle Issue; Product Quality Issue | Epipen Jr                               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
|   | Epipen Jr                               |                    |                    | S               |                           |                      |                 | Mylan      |                |
|   | Benadryl                                |                    |                    | C               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>                           | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 06-Mar-2018   | 14322387                                | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2017M1079023 |                      | 13 YR           | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>                          | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Expired Product Administered; Heart Rate Decreased; Needle Issue  | Epinephrine Injection Usp Auto-Injector |                    |                    | S               | Intramuscular             | 1 Df, Unk            |                 | Mylan      |                |
|   | Epipen Auto-Injector                    |                    |                    | S               | Intramuscular             | 1 Df, Unk            |                 | Mylan      |                |



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| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 08-Mar-2018  | 14613332                 | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2018M1006444 |                      |                 | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Needle Issue;                              | Epipen                   |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| No Adverse Event;  | Epipen                   |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| Product Quality Issue  | Epipen                   |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Mar-2018  | 14596018                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1013817 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Adverse Event; Injury Associated With Device | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 12-Mar-2018  | 14627121                 | EXPEDITED (15-DAY) |                    | DE              | JP-MYLANLABS-2018M1015126 |                      |                 | Unknown    | JPN            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death  | Epipen                   |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Mar-2018  | 14291160                 | EXPEDITED (15-DAY) |                    | HO, OT          | PT-MYLANLABS-2017M1077377 |                      | 22 YR           | Male       | PRT            |
| <u>Preferred Term</u>  | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; No Adverse Event; Product Quality Issue                      | Epipen                   |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
|  | Lepicortinolo /00016201/ |                    |                    | C               | Oral                      | Unk                  |                 | Mylan      |                |
|  | Zyrtec /00884302/        |                    |                    | C               | Oral                      | Unk                  |                 | Mylan      |                |
|  | Adrenaline /00003901/    |                    |                    | C               |                           |                      |                 | Mylan      |                |

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| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|------------------------------|-----------------|------------|----------------|
| 18-Mar-2018  | 14080646             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2017M1039095 |                              |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Device Issue; Headache; Lethargy; Nausea; Vomiting | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | Unk                          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 20-Mar-2018  | 14647109             | EXPEDITED (15-DAY) |                    | HO              | NZ-MYLANLABS-2018M1017059 |                              | 75 YR           | Female     | NZL            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; No Adverse Event   | Epipen               |                    |                    | S               |                           | Unk, Prn (Use When Required) |                 | Mylan      |                |
|  | Cilazapril           |                    |                    | C               | Oral                      | Unk                          |                 | Mylan      |                |
|  | Plendil              |                    |                    | C               | Oral                      | Unk                          |                 | Mylan      |                |
|  | Celol /00514701/     |                    |                    | C               | Oral                      | Unk                          |                 | Mylan      |                |
|  | Lactulose            |                    |                    | C               | Oral                      | Unk                          |                 | Mylan      |                |
|  | Losec /00661201/     |                    |                    | C               | Oral                      | Unk                          |                 | Mylan      |                |
|  | Lipex /00848101/     |                    |                    | C               | Oral                      | Unk                          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 21-Mar-2018  | 14292801             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2017M1078739 |                              | 9 YR            | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>           | <u>Duration</u> | <u>Mfr</u> |                |
| Device Defective; Injury Associated With Device                                    | Epipen Auto-Injector |                    |                    | S               | Subcutaneous              | Unk Unk, Prn                 |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>         | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 23-Mar-2018  | 14673190             | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2018M1018489 |                              |                 | Male       | AUS            |

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| <u>Preferred Term</u>  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
|--|--|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|----------------|----------------|
| Device Failure; No Adverse Event                                     | Epipen<br>Epipen                       |                    |                    | S<br>S          |                           |                      |                 | Mylan<br>Mylan |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 27-Mar-2018  | 14684702                               | DIRECT             | Y                  |                 |                           |                      | 26 YR           | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Altered State Of Consciousness; Device Malfunction; Drug Ineffective | Epipen                                 |                    |                    | S               |                           |                      |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 28-Mar-2018  | 14690789                               | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1020878 |                      |                 | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Glaucoma   | Epipen Auto-Injector                   |                    |                    | S               |                           | Unk                  |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 29-Mar-2018  | 14667509                               | EXPEDITED (15-DAY) |                    | LT, OT          | GB-MYLANLABS-2018M1018440 |                      | 52 YR           | Female         | GBR            |
| <u>Preferred Term</u>  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |
| Device Issue; No Adverse Event                                       | Epipen® Adrenaline Auto Injector 0.3mg |                    |                    | S               |                           | Unk, Once            |                 | Mylan          |                |
|  | Epipen® Adrenaline Auto Injector 0.3mg |                    |                    | S               |                           |                      |                 | Mylan          |                |
|  | Salbutamol                             |                    |                    | C               |                           | Unk                  |                 | Mylan          |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                          | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u>     | <u>Country</u> |
| 29-Mar-2018  | 14694163                               | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1018271 |                      | 52 YR           | Female         | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                         | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u>     |                |

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|  |   |                           |                             |                          |                               |                               |                             |                          |                         |
|--|---|---------------------------|-----------------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------|
| Device Failure; Drug Ineffective; Injection Site Haemorrhage; Injection Site Pain; Injection Site Swelling |   | Epipen Auto-Injector      | S                           |                          |                               | Unk                           |                             | Mylan                    |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 29-Mar-2018  | 14695886                                    | DIRECT                    | Y                           | RI, OT                   |                               |                               | 4 YR                        | Female                   | USA                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                     |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Anaphylactic Reaction; Laceration; Needle Issue  | Epipen Jr., 0.15mg/0.3ml Mg                 |                           |                             |                          | S                             |                               |                             |                          |                         |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 30-Mar-2018  | 14699570                                    | EXPEDITED (15-DAY)        |                             | LT, OT                   | CA-MYLANLABS-2018M1018712     |                               | 43 YR                       | Female                   | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                     |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Anaphylactic Reaction; Device Issue; Device Malfunction; General Symptom; Loss Of Consciousness            | Epipen                                      |                           |                             |                          | S                             | Intramuscular                 | 0.3 Mg, Once                |                          | Mylan                   |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 30-Mar-2018  | 14699572                                    | EXPEDITED (15-DAY)        |                             | OT                       | CA-MYLANLABS-2018M1018750     |                               | 30 YR                       | Female                   | CAN                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                     |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |
| Abortion Spontaneous; Maternal Exposure During Pregnancy   | Epipen® Jr. Adrenaline Auto Injector 0.15mg |                           |                             |                          | S                             | Intramuscular                 | 0.3 Mg, Unk                 |                          | Mylan                   |
| <a href="#">FDA Received Date</a>  | <a href="#">Case #</a>                      | <a href="#">Case Type</a> | <a href="#">Health Prof</a> | <a href="#">Outcomes</a> | <a href="#">Mfr Control #</a> | <a href="#">503B Facility</a> | <a href="#">Age</a>         | <a href="#">Sex</a>      | <a href="#">Country</a> |
| 02-Apr-2018  | 14706668                                    | EXPEDITED (15-DAY)        |                             | LT                       | UA-MYLANLABS-2018M1014783     |                               |                             | Female                   | GBR                     |
| <a href="#">Preferred Term</a>   | <a href="#">Product</a>                     |                           | <a href="#">Comp.</a>       | <a href="#">OTC</a>      | <a href="#">Role</a>          | <a href="#">Route</a>         | <a href="#">Dosage Text</a> | <a href="#">Duration</a> | <a href="#">Mfr</a>     |

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|  |                |                    |                    |                 |                           |                      |                 |            |                |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Issue; Needle Issue; No Adverse Event   |                | Epipen             |                    | S               | Intramuscular             | 0.3 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 02-Apr-2018  | 14706669       | EXPEDITED (15-DAY) |                    | LT              | GB-MYLANLABS-2018M1021777 |                      |                 | Female     | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Issue; Needle Issue; No Adverse Event   |                | Epipen             |                    | S               | Intramuscular             | 300 Mg, Prn          |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 03-Apr-2018  | 14321240       | EXPEDITED (15-DAY) |                    | OT              | JP-MYLANLABS-2017M1079615 |                      | 39 YR           | Female     | JPN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Device Use Issue; Drug Dose Omission; No Adverse Event; Product Quality Issue                    |                | Epipen             |                    | S               |                           | Unk                  |                 | Mylan      |                |
|  |                | Epipen             |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-Apr-2018  | 14516163       | EXPEDITED (15-DAY) |                    | OT              | CA-MYLANLABS-2018M1010190 |                      | 4 YR            | Female     | CAN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Device Failure; Device Use Issue; Drug Dose Omission; Needle Issue; Product Quality Issue |                | Epipen Jr          |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Apr-2018  | 14632684       | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1017211 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

|  |                |                    |                    |                 |                               |                       |                 |            |                |
|--|----------------|--------------------|--------------------|-----------------|-------------------------------|-----------------------|-----------------|------------|----------------|
| Feeling Abnormal;<br>Injection Site Pain; Needle<br>Issue; Palpitations; Tremor  |                | Epipen             |                    | S               | Intramuscular                 | Unk                   |                 |            | Mylan          |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Apr-2018  | 14692879       | EXPEDITED (15-DAY) |                    | HO, LT          | FI-MYLANLABS-<br>2018M1020005 |                       | 31 YR           | Female     | FIN            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Condition Aggravated;<br>Device Failure; Wrong<br>Technique In Product<br>Usage Process  | Epipen         |                    |                    | S               |                               | 300 Mg, Unk           |                 | Mylan      |                |
|  | Epipen         |                    |                    | S               |                               | 300 Mg, Unk           |                 | Mylan      |                |
|  | Epipen         |                    |                    | S               |                               |                       |                 | Mylan      |                |
|  | Epipen         |                    |                    | S               |                               |                       |                 | Mylan      |                |
|  | Epipen         |                    |                    | S               |                               |                       |                 | Mylan      |                |
|  | Epipen         |                    |                    | S               |                               |                       |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-Apr-2018  | 14735321       | EXPEDITED (15-DAY) |                    | OT              | US-OTSUKA-<br>2018_008053     |                       | 15 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Anxiety; Condition<br>Aggravated; Drug<br>Administered To Patient<br>Of Inappropriate Age;<br>Fatigue; Hypersensitivity;<br>Hypopnoea; Muscle<br>Tightness | Onzetra Xsail  |                    |                    | S               | Nasal                         | 11 Mg In Each Nostril |                 | Avanir     |                |
|  | Epipen         |                    |                    | S               | Unknown                       | Unk                   |                 |            |                |
|  | Zoloft         |                    |                    | C               | Unknown                       | Unk                   |                 |            |                |
|  | Fluticasone    |                    |                    | C               | Unknown                       | Unk                   |                 |            |                |
|  | Fluticasone    |                    |                    | C               |                               |                       |                 |            |                |
| <u>FDA Received Date</u>   | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>          | <u>503B Facility</u>  | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2018  | 14700217       | EXPEDITED (15-DAY) |                    | DE, OT          | GB-MYLANLABS-<br>2018M1021780 |                       | 11 YR           | Male       | GBR            |
| <u>Preferred Term</u>  | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>                  | <u>Dosage Text</u>    | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Shock;<br>Device Failure  | Epipen         |                    |                    | S               |                               | Unk                   |                 | Mylan      |                |

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### Detailed Report

| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|---|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 13-Apr-2018  | 14759854                                  | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1019536 |                      | 36 YR           | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Hypoaesthesia; Injection Site Pain; Prescription Drug Used Without A Prescription | Epipen Auto-Injector                      |                    |                    | S               | Unknown                   | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 13-Apr-2018  | 14759855                                  | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1019644 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Palpitations   | Epipen Jr. Auto-Injector                  |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 16-Apr-2018  | 13371043                                  | EXPEDITED (15-DAY) |                    | DE, OT          | AU-MYLANLABS-2017M1018398 |                      | 79 YR           | Male       | AUS            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Anaphylactic Reaction; Myocardial Infarction; Product Use Issue                                  | Epipen (Epinephrine) Auto Injector 0.3 Mg |                    |                    | S               |                           | 2 Df, Unk            |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2018  | 14494152                                  | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1008976 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>  | <u>Product</u>                            | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure   | Epipen Auto-Injector                      |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>   | <u>Case #</u>                             | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2018  | 14708814                                  | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1020915 |                      | 49 YR           | Female     | USA            |

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| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|---|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Contusion; Impaired Healing; Injection Site Injury; Injection Site Pain; Needle Issue; Pain | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2018   | 14769826             | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2018M1023828 |                      |                 | Male       | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 17-Apr-2018   | 14770446             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1021919 |                      | 49 YR           | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Accidental Exposure To Product; Device Breakage; Feeling Jittery                            | Epipen Auto-Injector |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2018   | 14734335             | EXPEDITED (15-DAY) |                    | OT              | AU-MYLANLABS-2018M1021151 |                      |                 | Male       | AUS            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; No Adverse Event  | Epipen               |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2018   | 14773290             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1022425 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>   | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Difficult To Use; Device Failure; Product  | Epipen Auto-Injector |                    |                    | S               | Unknown                   | Unk                  |                 | Mylan      |                |



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Quality Issue

| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 18-Apr-2018  | 14774443                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1024399 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Malfunction; Drug Dose Omission; Needle Issue | Epipen Jr. Auto-Injector |                    |                    | S               | Intramuscular             | 0.3 MI, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2018  | 14774552                 | EXPEDITED (15-DAY) |                    | OT              | IE-MYLANLABS-2018M1013966 |                      |                 | Female     | IRL            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; No Adverse Event                   | Epipen                   |                    |                    | S               | Intramuscular             | 300 Mg, Unk          |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 18-Apr-2018  | 14775758                 | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1023946 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure                                       | Epipen Auto-Injector     |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>                             | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 22-Apr-2018  | 13535849                 | EXPEDITED (15-DAY) |                    | HO              | CA-APOTEX-2017AP011461    |                      | 52 YR           | Male       | CAN            |
| <u>Preferred Term</u>                                | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Hypersensitivity                                     | Amlodipine               |                    |                    | S               | Oral                      | 10 Mg, Qd            |                 | Apotex     |                |
|  | Moxifloxacin             |                    |                    | S               | Ophthalmic                | Unk, Qd              |                 | Apotex     |                |
|  | Besivance                |                    |                    | S               | Unknown                   | Unk, Tid             |                 |            |                |
|  | Betoptic S               |                    |                    | S               | Unknown                   | Unk, Qd              |                 |            |                |
|  | Cialis                   |                    |                    | S               | Unknown                   | 2 Df, Qd             |                 |            |                |

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|                            |   |               |              |
|----------------------------|---|---------------|--------------|
| Cialis                     | S | Unknown       | Unk, Bid     |
| Cialis                     | S | Ophthalmic    | Unk          |
| Epipen                     | S | Intramuscular | Unk, Prn     |
| Nasonex                    | S | Nasal         | 2 Df, Qd     |
| Nasonex                    | S |               | Unk Unk, Qd  |
| Olopatadine                | S | Ophthalmic    | Unk, Prn     |
| Prednisolone               | S | Unknown       | Unk, Bid     |
| Prednisolone               | S | Unknown       | Unk, Tid     |
| Prednisolone               | S | Unknown       | Unk, Qid     |
| Prednisolone               | S | Unknown       | Unk, Qd      |
| Prednisolone               | S | Unknown       | 2 Df, Qd     |
| Prednisolone               | S | Unknown       | 3 Df, Qd     |
| Prednisolone               | S | Unknown       | 4 Df, Qd     |
| Prednisolone Teva          | S | Unknown       | 50 Mg, Qd    |
| Vigamox                    | S | Unknown       | Unk, Tid     |
| Vigamox                    | S | Ophthalmic    | Unk, Tid     |
| Besifloxacin Hydrochloride | S | Ophthalmic    | Unk Unk, Tid |
| Besifloxacin Hydrochloride | S | Ophthalmic    | Unk, Tid     |
| Betaxolol Hydrochloride    | S | Ophthalmic    | 1 Df, Qd     |
| Prednisone                 | S | Ophthalmic    | 50 Mg, Tid   |
| Prednisone                 | S | Unknown       | 50 Mg, Qd    |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 25-Apr-2018              | 14805741      | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2018M1027315 |                      |            | Male       | USA            |

| <u>Preferred Term</u>            | <u>Product</u>       | <u>Comp.</u> | <u>OTC</u> | <u>Role</u> | <u>Route</u> | <u>Dosage Text</u> | <u>Duration</u> | <u>Mfr</u> |
|----------------------------------|----------------------|--------------|------------|-------------|--------------|--------------------|-----------------|------------|
| Device Failure; No Adverse Event | Epipen Auto-Injector |              |            | S           |              | Unk                |                 | Mylan      |

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| <u>FDA Received Date</u> | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--------------------------|----------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 27-Apr-2018              | 14214063       | EXPEDITED (15-DAY) |                    | LT              | FR-MYLANLABS-2017M1073455 |                      |                 | Female     | FRA            |
| <u>Preferred Term</u>    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure           | Epipen         |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

| <u>FDA Received Date</u>                 | <u>Case #</u>  | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u>                    | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------|--------------------|--------------------|-----------------|---------------------------|---|-----------------|------------|----------------|
| 30-Apr-2018                              | 13253927       | EXPEDITED (15-DAY) |                    | OT              | SE-MYLANLABS-2017M1010570 |   |                 | Female     | SWE            |
| <u>Preferred Term</u>                    | <u>Product</u> | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>                      | <u>Duration</u> | <u>Mfr</u> |                |
| Wrong Technique In Product Usage Process | Epipen         |                    |                    | S               |                           | Unk                                     |                 | Mylan      |                |
|  | Betapred       |                    |                    | C               |                           | Unk, Prn                                |                 | Mylan      |                |
|  | Zyrlex         |                    |                    | C               | Oral                      | Daily Dose: 2 Df Dosage Form Every Days |                 | Mylan      |                |
|  | Tavegyl        |                    |                    | C               | Oral                      | 2 Df, Unk                               |                 | Mylan      |                |
|  | Tavegyl        |                    |                    | C               |                           |   |                 | Mylan      |                |
|  | Plavix         |                    |                    | C               | Oral                      |   |                 | Mylan      |                |
|  | Plavix         |                    |                    | C               |                           |   |                 | Mylan      |                |
|  | Renitec        |                    |                    | C               | Oral                      | 10 Mg, Unk                              |                 | Mylan      |                |
|  | Plendil        |                    |                    | C               | Oral                      |   |                 | Mylan      |                |

| <u>FDA Received Date</u>                             | <u>Case #</u>        | <u>Case Type</u> | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|--|----------------------|------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 04-May-2018  | 14790368             | NON-EXPEDITED    |                    |                 | US-MYLANLABS-2018M1026797 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                                | <u>Product</u>       | <u>Comp.</u>     | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; Drug Ineffective; Pruritus; Swelling | Epipen Auto-Injector |                  |                    | S               | Unknown                   | 1 Unk, Unk           |                 | Mylan      |                |
|  | Epipen Auto-Injector |                  |                    | S               | Unknown                   | Unk                  |                 | Mylan      |                |

| <u>FDA Received Date</u> | <u>Case #</u> | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u> | <u>Sex</u> | <u>Country</u> |
|--------------------------|---------------|--------------------|--------------------|-----------------|---------------------------|----------------------|------------|------------|----------------|
| 04-May-2018              | 14841376      | EXPEDITED (15-DAY) |                    | HO              | GB-MYLANLABS-2018M1028063 |                      |            | Unknown    | GBR            |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
|--|----------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| Device Failure; Needle Issue; No Adverse Event | Epipen Junior        |                    |                    | S               |                           | 0.15 Mg, Unk         |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-May-2018                                    | 14849338             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1030531 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Dizziness; Heart Rate Increased                | Epipen               |                    |                    | S               | Intramuscular             | 3 Mg, Unk            |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 04-May-2018                                    | 14849339             | NON-EXPEDITED      |                    |                 | US-MYLANLABS-2018M1030577 |                      |                 | Female     | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Intentional Product Misuse; No Adverse Event   | Epipen               |                    |                    | S               | Intramuscular             |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 07-May-2018                                    | 14852493             | NON-EXPEDITED      |                    | HO, LT, OT      | US-PFIZER INC-2018180335  |                      |                 | Male       | USA            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective                               | Epipen               |                    |                    | S               | Unknown                   | Unk                  |                 | Unknown    |                |
| <u>FDA Received Date</u>                       | <u>Case #</u>        | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-May-2018                                    | 14826234             | EXPEDITED (15-DAY) |                    | HO, LT          | GB-MYLANLABS-2018M1028576 |                      |                 | Male       | GBR            |
| <u>Preferred Term</u>                          | <u>Product</u>       | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Device Failure; No Adverse Event               | Epipen Auto-Injector |                    |                    | S               |                           | Unk                  |                 | Mylan      |                |

# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
|---|--------------------------|--------------------|--------------------|-----------------|---------------------------|----------------------|-----------------|------------|----------------|
| 09-May-2018   | 14869976                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1029342 |                      |                 | Male       | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Drug Ineffective; Expired   | Epipen                   |                    |                    | S               | Intramuscular             | Unk Mg, Unk          |                 | Mylan      |                |
| Product Administered;   | Epipen                   |                    |                    | S               | Intramuscular             | Unk                  |                 | Mylan      |                |
| Product Storage Error   |                          |                    |                    |                 |                           |                      |                 |            |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 09-May-2018   | 14871723                 | EXPEDITED (15-DAY) |                    | OT              | US-MYLANLABS-2018M1029979 |                      |                 | Unknown    | USA            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Injection Site Laceration; Needle Issue   | Epipen Jr. Auto-Injector |                    |                    | S               |                           |                      |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-May-2018   | 14475272                 | EXPEDITED (15-DAY) |                    | DE, OT          | CA-MYLANLABS-2018M1006783 |                      |                 | Male       | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Death; Expired Device Used  | Epipen                   |                    |                    | S               | Unknown                   | Unk                  |                 | Mylan      |                |
| <u>FDA Received Date</u>  | <u>Case #</u>            | <u>Case Type</u>   | <u>Health Prof</u> | <u>Outcomes</u> | <u>Mfr Control #</u>      | <u>503B Facility</u> | <u>Age</u>      | <u>Sex</u> | <u>Country</u> |
| 10-May-2018   | 14877409                 | EXPEDITED (15-DAY) |                    | HO, OT          | CA-MYLANLABS-2018M1030972 |                      |                 | Unknown    | CAN            |
| <u>Preferred Term</u>   | <u>Product</u>           | <u>Comp.</u>       | <u>OTC</u>         | <u>Role</u>     | <u>Route</u>              | <u>Dosage Text</u>   | <u>Duration</u> | <u>Mfr</u> |                |
| Circumstance Or Information Capable Of Leading To Medication Error; Drug Ineffective; Product Use Issue | Epipen                   |                    |                    | S               | Unknown                   |                      |                 | Mylan      |                |